federal register

Friday
November 21, 1980

Part IV

Environmental Protection Agency

Proposed Environmental Standards; and Proposed Good Laboratory Practice Standards for Physical, Chemicals, Persistence, and Ecological Effects Testing

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 772

[OPTS 46007; TSH FRL 1594-3]

Environmental Test Standards; Proposed Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This notice proposes a portion of the Agency's standards for development of certain data on physical and chemical characteristics of substances for which EPA will require testing under section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469; 90 Stat. 2006; 15 U.S.C. 2603). These standards will be incorporated into future TSCA section 4 rules that will designate particular chemicals for testing. When EPA requires testing on specific chemicals, the person performing the test will be required to conform to the methods and conditions in these standards with such modifications as may be appropriate for the specific chemical. The Agency will use the data generated by such testing to aid in assessing whether chemicals present unreasonable risks. EPA is proposing here preliminary standards for testing density/relative density, melting temperature, vapor pressure, octanol/water partition coefficient, and soil thin layer chromatography.

DATES: Written comments should be submitted on or before January 21, 1981. Oral comments will be received on February 10, 1981. See Supplementary Information for public meeting information.

ADDRESSES: Written views and comments should bear the EPA document control number [OPTS-46007] and should be submitted to: Document Control Officer (TS-793), Management Support Division, Office of Pesticides and Toxic Substances (OPTS), Environmental Protection Agency, Rm. E-447, 401 M St., SW., Washington, D.C. 20460, (202-755-8050).

See SUPPLEMENTARY INFORMATION, PUBLIC MEETINGS; for location of public meeting.

FOR FURTHER INFORMATION CONTACT: John B. Ritch, Jr., Industry Assistance Office (TS-799), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-427, 401 M St., SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404).

SUPPLEMENTARY INFORMATION:

I. Introduction

Support documents which provide the scientific and technical bases for the test standards proposed in this package are available upon request from the Industry Assistance Office (TS-799), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-427, 401 M Street, SW., Washington, D.C. 20460. The support documents, when read together with this preamble, will provide an explanation of the bases for these standards.

EPA proposed under section 4 of the Toxic Substances Control Act (TSCA)(Pub. L. 94-469; 90 Stat. 2006; 15 U.S.C. 2603) standards for the development of data on chronic health effects published in the **Federal Register** of May 9, 1979 (44 FR 27334 et seq.). With the proposal, EPA began the process of codifying health effects standards for incorporation into future TSCA section 4 test rules. EPA proposed standards for testing chemicals for acute and subchronic toxicity, mutagenic effects, teratogenic effects, reproductive effects, and standards for metabolism studies published in the **Federal Register** on July 26, 1979 (44 FR 44054). Today EPA is continuing the process of codifying test standards by proposing the first environmental testing standards.

In the future, the Agency will propose chemicals to be tested in accordance with section 4 test standards. In the present rulemaking to codify test standards, the issues center on the suitability of the proposed generic standards for testing chemicals under these future section 4 test rules. In rulemakings to require the testing of specific chemicals or categories of chemicals, the issues will center on the need to test the identified chemicals, and the appropriateness of any needed modifications to those generic standards when applied to particular chemicals.

In the future EPA will be proposing additional test standards for neurobehavioral toxicity, other physical, chemical, and environmental persistence characteristics, and various ecological effects. In addition, EPA has proposed a set of Good Laboratory Practices (GLP) for use with test standards on human health effects (44 FR 27334), and in a separate proposal in this issue of the **Federal Register** EPA is proposing a GLP for use with test standards on ecological effects and on chemical, physical, and environmental persistence characteristics.

The Agency's goal is to promulgate test standards for every important environmental effect and for the physical, chemical, and persistence characteristics which can be used in judging the environmental fate of a chemical. The Agency does not intend to require the use of all or even necessarily a significant fraction of the available test standards in a given test rule that requires testing of a specific chemical. Testing requirements will only be applied to a specific chemical if the Agency finds such testing is necessary in accordance with section 4 of the Act.

When EPA determines that chemical substances satisfy the testing prerequisites in section 4(a), these chemical substances will be joined in section 4(a) test rules with standards finalized as a result of today's proposal, or with revisions or modifications of these standards, as necessary and appropriate.

EPA's legal authority to require testing of chemical substances in accordance with test standards and the use of test data for assessing the risk potential of toxic substances are set forth in the document proposing Chronic Health Effects Standards published in the **Federal Register** of May 9, 1979 (44 FR 27335).

II. Major Issues

Several informal comments received by EPA in response to earlier drafts of these standards and some written and oral comments on published proposed standards for testing for health effects have raised two major questions:

(1) Why is EPA issuing "generic" test standards rather than preparing and proposing test standards as part of each rule?

(2) Why are TSCA proposed test standards generally more detailed and specific than standards or guidelines used by other agencies or used by EPA in other programs?

The following discussion explains EPA's reason for the use of generic standards and for preparing test standards with a relatively high degree of specificity.

"Generic" Standards

As explained in other places in this proposal, EPA is developing test standards for application in section 4 testing rules. Steps in the process are:

1. EPA prepares proposed test standards and publishes them for public comment.

2. EPA revises the standards, considering comments received, and issues the standards as rules published in the Code of Federal Regulations.

3. When the Agency proposes rules that require testing of individual chemicals, the proposed rule will incorporate test standards as appropriate. In the proposed rule, the

Agency may modify the standards as needed because of characteristics peculiar to the chemicals addressed by the rule. During the public comment period on each test rule, the issues for comment will focus on the appropriateness of testing the chemical and the need to modify the standards based on specific chemical characteristics.

4. In chemical-specific test rules, the Agency normally will not modify the basic standards except as applied to individual chemicals. At regular intervals, but at least once each year as required by TSCA, EPA reviews all test standards and proposes modifications as necessary.

The alternative would be for EPA to create new standards for testing in each test rule. Thereby, as each proposed testing rule is issued, all details of the testing standards for each prescribed test would be included with the proposed rule. Each aspect of each test standard also would be open for detailed comment as part of the commenting on the proposed rule.

EPA's reasons for developing standards separately are:

(1) Section 4 of TSCA requires that EPA assure that testing of chemicals produces data that are "reliable and adequate". This means, for example, that the methods prescribed must be reviewed and validated. Since testing conditions may be chemical specific, it simply is neither practical nor efficient for EPA to validate testing methods for each rule; it is necessary to have a basic set of validated and accepted generic standards which have received reviews and acceptance that can be applied as the rules demand, with modifications as necessary for particular chemicals.

(2) EPA must have an orderly process for annual review of standards. Section 4(b)(2)(B) of TSCA mandates that standards for testing be reviewed at least every 12 months. EPA plans to conduct these reviews through two processes:

(a) A review of existing standards by its own scientists and invited scientists from outside the Agency.

(b) Solicitation of comments from all interested parties through public announcement of an open period of consideration of review.

In order for such an orderly review process to work, it is necessary for EPA to have specific objects of review in the form of uniform standards for testing that are used in the many different rules. Again, it is not practical and would be extremely difficult to review a set of standards if the standards were scattered among a host of differing rules, with differences in the standards from rule to rule.

(3) EPA is obligated to develop testing standards that are, to the extent practicable, consistent with standards of other agencies, with standards of other EPA programs, and with accepted international standards for testing of chemicals. In most cases these are generic standards and do not apply to specific chemicals or chemical groups. Standards for TSCA testing will of course differ in many ways in order to meet the specific requirements of the Agency for assessing risk of chemicals under TSCA. So-called "generic" standards allow EPA a practical basis for examining the standards of other organizations and programs, judging their suitability for application to TSCA testing, making modifications as necessary, securing comment, conducting regular reviews of the changes in the state-of-the-art and the standards developed by others, and incorporating the changes in TSCA standards.

(4) EPA wants to encourage manufacturers to test chemicals on their own initiative. EPA feels that a set of acceptable standards for conducting tests provides manufacturers with a good set of guidance as to the standards of data that they should seek to achieve in their own testing programs.

Specificity

Section 3(12)(B) of TSCA states that "standards for the development of test data" means, to the extent necessary, a prescription to assure that data respecting such effects and characteristics are reliable and adequate:

(i) The manner in which such data are to be developed.

(ii) The specification of any test protocol or methodology to be employed in the development of such data.

(iii) Such other requirements as are necessary to provide such assurance.

There are many aspects to EPA's requirements for reliable and adequate data:

(1) EPA must be able to judge the accuracy and precision of the data. By use of a relatively small number of methods that have been validated and standardized, EPA is able to compile information on the accuracy and precision of prescribed tests. If EPA were to allow great freedom in the selection or alteration of testing methods, it would be necessary to require each tester to submit data on validation, precision, and accuracy with each set of data.

(2) EPA must be able to prescribe that certain data fall within specified levels of accuracy. Examples are data that EPA uses in certain models predicting environmental fate, exposure, or toxicity to certain parts of the environment. The most practical way to prescribe accuracy is to specify standardized techniques which have been validated as being capable of meeting the accuracy requirements which the Agency needs.

(3) Certain types of testing data are used in risk analyses which require data that are highly comparable to use in interpolation, extrapolation, or evaluation of surrogates. EPA, for example, uses toxicity or reproductive tests on a few species of aquatic plants and animals to judge whether or not chemicals have effects on the overall aquatic environment. The test species have been carefully selected and the testing schemes have been made highly specific in order for EPA to make broad analyses of environmental impact based on the results of a few tests. Without the strict standards on the few types of tests which EPA uses as surrogates, it would be necessary for the Agency to require a much larger group of tests.

(4) It is necessary to prepare testing standards for dealing with the least experienced laboratories. Although many laboratories have highly experienced scientific staffs and facilities and normally conduct chemical tests in professional, reliable manners, there are others who do not. In the cases of the best laboratories it would probably be possible to expect adequate and reliable data based only on general guidance for testing methodology. But with the less experienced laboratories, the staff are not able to make adequate judgments as to which specific testing standard to apply and where the standards may or may not be altered without adversely affecting the results. EPA, therefore, feels that it must write standards that are specific so as to provide adequate guidance to the least experienced testing laboratories as to which specific techniques must be used and which portions of the testing protocols may or may not be modified.

In order to meet the four requirements stated above, and others, and to assure comparability of data among chemicals and laboratories it is necessary to limit many of the discretionary variations which are often permitted in testing protocols. For these reasons, the standards for TSCA section 4 testing specify detailed instructions to assure that reliable data are developed to satisfy the needs of EPA for good information to conduct chemical risk assessments.

In spite of the specificity, these standards are general in several

respects, and where necessary, more specific requirements or modifications related to the chemical substance(s) to be tested may be proposed in specific chemical test rules.

See Good Laboratory Practice Standards for Health Effects (44 FR 27362) for a discussion of the problem of unreliable test data.

III. Basis and Purpose of Physical, Chemical, and Environmental Persistence Test Standards

General

Testing of physical, chemical, and environmental persistence characteristics will be required as part of a test rule in those cases were the Agency determines that data from such testing are necessary to evaluate the environmental fate or other pertinent characteristics of a chemical.

Assessment of the fate of a chemical substance after its release into the environment often is essential for the evaluation of exposure and risks posed by that chemical. Fate, in this sense, is defined as the transport and transformation of a chemical by natural means after it is released to the environment from a point source, e.g., a manufacturing plant or waste treatment plant, a disposal site such as a landfill, or a dispersive use. Determination of the fate of a chemical substance in the environment may involve investigation of the nature of dispersal and ultimate distribution, and of the types and rates of reactions in which the chemical participates during transport. Fate determinations help to identify the chemical form(s), the environmental compartments or concentration ranges to which the environment will be exposed, and the organisms exposed to the chemical.

Chemical Transport

Chemicals discharged into the environment are generally released into one or more of four media: air, water, soil, and sediment. Discharged materials often do not reside long in one medium but are transported to other media by processes that depend upon the characteristics of the region into which they are released, e.g, meterological conditions, the flow of surface waters, the location and flow of groundwaters, tidal action, topographic characteristics, and the characteristics of soils, sediments, and suspended particulates, and on certain physical and chemical characteristics of the substance itself. An analysis of the transport of discharged chemicals is further complicated because receiving and transporting media can be divided into a variety of subtypes. For example, water can be fresh, saline, estuarine, undergound, or free-flowing in streams, or ponded in lakes. Similarly, soils may vary in structure, composition, and chemical properties.

Several methods are available for helping to determine the tendency of a chemical to become distributed into one or more environmental media following its release, i.e., its partitioning potential. One of these methods is direct field measurement or monitoring. A very small portion of all chemicals, however, has been the object of field study or monitoring programs and, therefore, existing monitoring data usually are not available for adequately determining partitioning potential. In addition, monitoring is expensive and generally requires a considerable amount of time to accomplish. Most determinations of chemical transport must therefore depend, at least in part, on analyses of several important chemical and physical characteristics, such as: (1) density; (2) melting and boiling temperatures; (3) octanol/water partition coefficients; (4) solubility in water; (5) vapor pressure; (6) adsorption/desorption on particulate surfaces; (7) particle size distribution for insoluble solids; (8) dissociation constants in water for substances which dissociate in water; and (9) ultraviolet and visible absorption spectra.

The test standards proposed in this **Federal Register** notice are detailed descriptions of methods for measuring several of the characteristics mentioned above. They have been evaluated by EPA and have been found suitable for developing good and reliable data as required under section of TSCA. Some of the methods have been selected from those adopted by standardizing organizations; but others have been developed by or for EPA, or adopted from other sources as the needs of EPA dictated.

Chemical Persistence

Chemical persistence can be defined as the ability of a chemical to retain its molecular integrity, and its physical, chemical, and functional characteristics in the environment through which it is transported and distributed following its environmental release. The inverse of chemical persistence is chemical degradability or transformation, which can be brought about through physical, biological, chemical, and photochemical mechanisms.

The susceptibility or resistance of a chemical to degradation will determine, to a large extent, its residence time in a particular medium, environmental compartment, or ecosystem. Persistence is a major factor in determining the steady-state concentration that a chemical may attain in a particular medium or in a compartment thereof, i.e., its residence time. Thus, if the rate of degradation in a medium or environmental compartment exceeds its rate of entry, there is less likelihood of its achieving significant environmental concentration levels in that medium or compartment. However, there could still be cause for concern if the rate of uptake by biota in those areas exceeded the rate of chemical degradation, or if dispersion or transport were poor so that the chemical tended to concentrate in small "hot spots," areas of relatively high concentrations of a chemical.

Data on chemical persistence and on chemical transport can assist in making pretesting decisions such as the selection of species to test for chemical effects. Thus, if data on persistence and transport showed that it is likely that a chemical will concentrate or persist in a particular environment, it might be logical to test for effects on a wide variety of species residing in that environment.

As stated above, degradation of chemical substances can take place by physical, biological, chemical, and photochemical mechanisms. The test standards found in Subpart L describe what EPA believes are some of the best "screening" tests for assessing potential degradability by each mechanism. As EPA and the scientific community develop more sophisticated test mechanisms, EPA's test standards for measuring chemical persistence will address the following: (1) biodegradation—aerobic and anaerobic, (2) photochemical degradation—aquatic and atmospheric, and (3) chemical degradation—hydrolytic, reductive, and oxidative.

General Criteria for Test Selection

Test methods described in Subpart L are selected on the basis of several criteria. First, the selected methods must be capable of providing information precise enough for use in risk assessments. Selected methods also must be cost effective and be recognized by the scientific community as part of the state-of-the-art technology. Exceptions may be made when intensive surveys of the literature indicate that there are deficiencies in the state-of-the-art, such as with tests that do not answer the important questions, are poorly validated, or are inadequately described. When this occurs, hybrid tests incorporating the best features of several methods will be constructed for interim use pending the development of better methodologies and validation of

the hybrids themselves. Where problems of this type have been identified, EPA is vigorously seeking solutions through development of new tests or validation of recently developed tests that are not yet widely accepted.

IV. Scientific Policy Considerations

General

The major question which applies to all types of tests which generate data to be used in predicting environmental effects and the fate of chemical substances is the validity of using laboratory results to make predictions of chemical behavior in the "real world". Extrapolation of the results of controlled laboratory tests to predictions of the environmental behavior of chemicals is accepted practice. The alternative of testing in the environment itself is often impractical for a number of reasons. The environment is a heterogeneous entity with endless variations. Therefore, direct testing in the environment is usually limited to cases in which the specific area of chemical release is known and there is adequate assurance that the chemical would be fully contained within the proscribed area. In the absence of these conditions, field testing is often economically prohibitive and could be hazardous if chemicals of unknown toxicity were to be applied to the environment.

Since it is impossible to simulate all environments, generic testing standards must address a representative set of relevant environmental variables, chosen to be economically and technically practical. The Agency specifically solicits comment from interested parties on the adequacy with which this objective would be met by the proposed standards.

Relationship to EPA Pesticide Registration Guidelines

EPA's Office of Pesticide Programs has proposed testing guidelines under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136 et seq.) which contain data requirements comparable to those proposed by these standards published in the **Federal Register** of August 22, 1978 (43 FR 37336). In addition, EPA and other Federal agencies may issue regulations under other statutory authorities which would impose requirements similar to those in these standards. The Agency's policy is to reduce the burden on the regulated public which might arise from conflicting requirements under these different sets of regulations and guidelines.

Proposed test standards to meet TSCA and FIFRA requirements differ to some extent because of the Agency's need to evaluate a greater variety of chemicals and exposure situations under TSCA, and the continuing evolution of technology. For example, chemicals registered under FIFRA are known biocides and have been developed for their intentional release and destructive effects on various types of organisms. On the other hand, under TSCA, the Agency must evaluate the effects of a variety of chemicals whose harmful effects and exposure routes may or may not be known. It is logical, therefore, that EPA may take different approaches to testing these two classes of materials.

The final TSCA test standards and final FIFRA guidelines will be consistent to the extent practical. In this proposal, the major differences are that TSCA test standards include broader ranges of testing techniques within each test standard as a result of the greater variety of chemicals which may be subjected to testing under TSCA. Also, the TSCA test standards provide instructions to the tester on the selection of an appropriate technique from among those cited in the standard whereas the FIFRA guidelines do not.

A more specific discussion of the differences between individual TSCA and FIFRA standards appears in the support document of each proposed TSCA test standard.

Relationship to Interagency and International Test Guidelines

EPA is participating in two major efforts to develop multiagency agreement on test methods—one interagency and one international. EPA has joined with the Food and Drug Administration (FDA of DHHS), the Consumer Product Safety Commission (CPSC), and the Occupational Safety and Health Administration (OSHA of DOL) and the Food Quality and Safety Service (FQSS of USDA), to form the Interagency Regulatory Liaison Group (IRLG). The general purpose of the IRLG is to coordinate the regulatory activities of the five member agencies. One IRLG committee, in which EPA participates, is developing testing guidelines for human health and environmental effects. The guidelines so developed are intended to yield data acceptable to all five agencies. When proposed IRLG testing guidelines are completed, EPA will review and revise its test standards to be consistent with IRLG guidelines, to the extent that EPA's statutory responsibilities will permit.

EPA also is working with the IRLG and other agencies in the development of schemes for standardized reporting formats and improved recordkeeping and reporting. The present plan is for IRLG to announce the availability of its reporting formats as it announces the availability of its standards. To the extent practical, EPA will adopt the same reporting formats for use in reporting data from the tests outlined in these standards.

In developing chemical testing and other activities under TSCA, EPA has been a full and regular partner in extensive international consultations and activities, especially through the Organization for Economic Cooperation and Development (OECD). The Agency places high priority on these international activities and will attempt to achieve an international harmonizing of chemical testing requirements. A principal objective is to reduce the burden on the international chemical industry which might be caused by unnecessarily vague or inconsistent requirements. To the extent practical under laws of the several countries, the objective is to provide that data developed to meet one country's requirements are acceptable to another.

Comments from other countries and international organizations will be solicited and given serious consideration as the Agency develops these and other regulations. Agreement reached through the international activities in which the EPA is engaged will be considered in EPA development of regulations subject to the strictures of the Agency rulemaking process.

Future Environmental Test Standards

The Agency intends to promulgate test standards which can be applied selectively, as necessary, to obtain data on all factors which need to be known to assess a chemical's environmental effects and fate. The standards proposed here are only part of a group of tests needed to characterize chemicals and that group, in turn, is a subset of a broader category of test standards on physical, chemical, and environmental persistence characteristics.

Over the next several months the Agency also will be proposing a full range of test standards for ecological effects, ranging from simple, short-term acute toxicity tests to more complex life-cycle testing, and covering organisms found in the major compartments of both the aquatic and terrestrial environments.

The Agency currently is involved in a major research effort to develop and validate additional testing methodologies at both ends of the spectrum of complexity. A number of protocols designed to provide rapid,

inexpensive screening of chemicals for ecological effects are being investigated currently. The Agency also is pursuing complex testing systems which enable quantification of effects above the population level of ecological organization.

V. Economic Analysis

The economic analysis of test standards has two major parts. The first part involves analyzing the cost of the individual tests outlined in the standards, or the cost of the protocols associated with these standards. The second part will occur when these test standards are referenced in test rules for specific chemicals and chemical groups. The second analysis will consider the potential economic impact of these costs on the parties involved, e.g., manufacturers and/or processors.

Economic analyses for the standards proposed here are included in the support documents and in a report by Enviro Control, Inc., which is part of the public record for this rulemaking. The analyses cover only the costs of the procedures associated with these standards. The estimates were prepared from a survey of commercial laboratories, and by separating the protocol into components and estimating the cost of each component, including direct labor cost, overhead cost, other direct costs, general and administrative costs, and profit or fee. Estimates of the costs of the five tests proposed here are:

1. For density/relative density the range is $13 to $109 per test.

2. For melting temperature the range is $25 to $125 per test.

3. For vapor pressure the range is $64 to $595 per test, depending on the characteristics of the chemical and the protocol used. There may be additional costs of up to approximately $1,000 for chemical analyses, again depending on the type of material being tested.

4. For octanol/water partition coefficient the range is $100 to $1,400 per test, which may be reduced significantly if several tests are run at once. There may be additional costs of chemical analyses which will not exceed $1,000 per sample for most materials.

5. For soil thin-layer chromatography the range is $172 to $850 per test. For some chemicals there may be additional costs of chemical analyses which will not exceed $1,000 per sample for most materials. All of the above cost estimates assume that the proposed Good Laboratory Practice Standards apply to the testing.

When the Agency applies these test standards to test rules for specific chemicals and chemical groups, it will analyze the potential economic impact of these test rules on the parties subject to the rules. This analysis will consider the market, financial, and economic conditions of the chemicals involved, either as individual chemicals or as members of a group. It will consider the impact of the test costs on production, by considering such items as price changes, demand elasticities, and the availability of substitutes, and it will consider the ability of the income from a chemical to support testing required. The economic impact analysis of the combination of tests will be presented in support documents when the test rules are proposed; they will be subjected to public comment, and revised if needed. Economic factors relating to individual tests will be considered in developing all test rules.

VI. Public Meetings

EPA personnel responsible for developing these proposed Environmental Test Standards will be available to meet with interested persons from companies, trade associations, organized labor and citizen organizations on February 10, 1981 at: Skyline Inn, South Capitol & I Streets, SW., Washington, D.C.

The meeting will be from 1 p.m. to 5 p.m. This location is three blocks east of the EPA Headquarters, Waterside Mall, 401 M St., SW., Washington, D.C. Persons who wish to make presentations should request time by contacting the Industry Assistance Office by telephone, either toll free (800–424–9065) or on 554–1404 in Washington. Time will be scheduled between 1 p.m. and 5 p.m. The Agency will make a transcript of the sessions for inclusion in the official public record. Participation in a session will be limited to those who have requested that time to make oral comment.

One purpose of providing this opportunity for oral comment is to provide EPA with information on costs and approaches to compliance for impacted companies, especially small ones. The other purpose of this public meeting is to allow EPA to digest the scope and nature of written comments on scientific and technical points before hearing oral argument or comment on them. The Agency's general criterion for alloting time will be that a person has an interpretation, data or experience that is best presented orally with the opportunity for cross-checking communication with the Agency. In this case, an additional criterion will be that a person has a review of the written commentary already submitted to share with the Agency. EPA's experience has shown that this roundtable format for public meetings by request that are open to the public yields more productive exchanges for both commentators and the Agency. EPA encourages commentators to use the toll free telephone to ask questions of clarification early in the written comment period to aid their formulating their comments.

VII. Public Record

EPA has established a public record for this rulemaking docket number [OPTS 46007] which along with a complete index is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m. (Rm. E–447, 401 M St., SW., Washington, D.C. 20460). This record includes basic information considered by the Agency in developing this proposal. The Agency will supplement the record with additional information as it is received. The record includes the following information:

1. USEPA–OPTS. "Proposed Environmental Effects Test Standards for Toxic Substance Control Act Test Rules."

2. USEPA–OPTS. "Proposed Environmental Effects Test Standards for Toxic Substance Control Act Test Rules." Support Documents.

3. USEPA–OPTS. "Toxic Substances Control Act Premanufacture Testing of New Chemical Substances" (44 FR 16240) and all public comments received on this discussion document.

4. Drafts of the proposed rules, the preamble, and the support documents which were available for public comment.

5. Correspondence pertaining to the development of the standards, the preamble, or the support document. This does not include inter- or intra-agency correspondence, unless specifically noted in the index to the rulemaking record.

6. Minutes, summaries, or transcripts relating to public meetings held to develop the standards.

7. Scientific papers relevant to issues relating to these tests which were used by the Agency in developing this proposal.

8. Contractor's report, "Cost Analysis Methodology and Protocol Estimates: Environmental Standards," by Enviro Control, Inc., April 28, 1980, p. 26.

Published documents cited in this preamble are incorporated in the record by reference. EPA will accept additional and relevant material for the record at any time between this proposal and the final designation of the rulemaking record, on or before the date of promulgation of these requirements as prescribed by TSCA section 19(a)(3). During the rulemaking proceeding, interested persons should notify EPA of

additions they believe should be made to the record. EPA particularly encourages this notification during the early part of the comment period.

VIII. Proposed Test Standards

The following introductory material applies to the five specific test standards included in this proposal:

Density/Relative Density

The density of a substance influences movement of a chemical in the environment. Solids and liquids will float or sink in water depending on their density, and lightweight granular materials will be more easily transported in the air than will heavy materials. Tests for determining density are inexpensive and most testing laboratories will be able to run the tests with at least the accuracy required by EPA.

The test standard requires sponsors to determine density or density relative to water or air (relative density) at ambient temperature. It is written in a general way, to permit the selection of a technique appropriate to the particular chemical from a variety of available techniques. These techniques were selected on the basis of their relatively low cost and acceptability by the scientific community as outlined in the support document. A theoretical calculation of density is specified for gaseous materials, but the measurement of real gas density is permitted as an option.

Factors that influence the selection of a technique for a liquid test material include volatility and viscosity. Factors that influence the selection of a technique for a solid test material include particle size, wetability by possible immersion liquids, and solubility in possible immersion liquids. The test is to be performed at standard reference temperatures.

Melting Temperature

The melting temperature describes whether a chemical substance or mixture will be solid or fluid under ambient pressure. This information will allow the Agency to determine the form in which the chemical will be found when in the environment. The form is important because it determines whether the chemical will stand in place or flow away from spills, stockpiles, or places of use or disposal. When combined with density information and solubility information it determines how the chemical will move in a waterway; when combined with other information such as volatility and particle size, it determines the distribution and dispersal of the material.

Melting temperature is the temperature at which the change from solid to liquid takes place. In practice many materials, particularly those that are mixtures or form glasses, do not melt sharply at a well defined temperature, but rather soften and liquify over a range of temperatures. For these materials other terms are used, including pour point, congealing temperature, initial and final melting temperature, or melting range. In addition, impurities influence the melting temperature, sometimes by many degrees.

The proposed test standard would require sponsors to determine melting temperature of the test chemical or the range of temperature over which it melts, within the range from −30°C to +250°C. Ambient temperatures in the United States rarely go below −30°C in the winter and above 43°C in the summer. Higher temperatures, such as are caused by the sun shining on dark surfaces or by heated apparatus, give an upper limit of interest of 250°C. Most environmental surfaces are below this temperature at all times and even heated apparatus cools below this temperature within minutes after being turned off. The standard is written to permit selection of an appropriate technique from a spectrum of techniques selected on the basis of their relatively low cost and acceptability to the scientific community as outlined in the support document.

Vapor Pressure

The vapor pressure of a chemical affects the tendency of a substance to volatilize, and therefore is important in determining the environmental fate of the chemical.

Volatilization is the loss of a substance from a surface or from solution by evaporation, and volatilization from land and water surfaces is the most important source of material for airborne transport. Volatilization is probably the single largest means by which pesticides are lost and transported over wide areas and into bodies of water far from the application location. The airborne vapors of a hazardous chemical may present a threat to humans and other life exposed to those vapors, not only in the areas of chemical release but also at sites remote from the volatilization site. This occurs when vapors are removed from the air, primarily by precipitation with rain or snow.

There are several procedures for the measurement of vapor pressure. These include static procedures, boiling point procedures, methods of vapor transfer by a current of inert gas ("gas saturation" or "transpiration" techniques), evaporation from an open surface, and effusion procedures. There are also many specialized techniques that have been used for very precise vapor pressure determinations of specific kinds of materials or for micro and semimicro determinations.

A procedure for measuring the vapor pressure of materials released to the environment ideally would cover a wide range of vapor pressure values, at ambient temperatures. No single procedure can cover this range, so two different procedures are described in this test standard, each suited for a different part of the range. The isoteniscope procedure is for pure liquids with vapor pressures from 0.1 to 100 kPa. For vapor pressure of 10^{-5} to 10^{3} Pa, a gas saturation procedure is to be used.

The isoteniscope procedure uses a standardized technique that was developed to measure the vapor pressure of certain liquid hydrocarbons. The sample is purified within the equipment by removing dissolved and entrained gases until the measured vapor pressure is constant, a process called "degassing." Impurities more volatile than the sample will tend to increase the observed vapor pressure. Results are subject to only slight error for samples containing non-volatile impurities.

The gas saturation procedures described utilize relatively simple equipment. Results are easy to obtain and can be quite precise. The same procedures also can be used to study volatilization from laboratory-scale environmental simulations.

Octanol/Water Partition Coefficient

The tendency of an organic chemical to bioconcentrate in living cells can be inferred from the value of the octanol/water partition coefficient, K_{ow}. Chemicals with K_{ow} less than 10 will not significantly partition into, or tend to accumulate in, living cells. Chemicals with K_{ow} greater than 10^{6} will tend to accumulate. Chemicals that exist in the environment at subtoxic levels may bioconcentrate to toxic levels once inside organisms.

This test standard describes a detailed and commonly used procedure for determination of the octanol/water partition coefficient K_{ow} for organic chemicals. The method determines the distribution of the chemical between octanol and water after equilibration. Values of K_{ow} can then be calculated from the resulting data. The test standard is designed to determine the octanol/water partition coefficient of the test chemical in the range 10 to 10^{6}. For chemicals whose values lie outside

this range, K_{ow} should be characterized as less than 10 or greater than 10^6 with no further quantification.

Other methods for determining or estimating partition coefficients such as reverse phase-high pressure liquid chromatography were rejected for reasons presented in the support document.

Soil Thin-Layer Chromatography

Soil thin-layer chromatography (TLC) is a qualitative screening method for estimating a chemical's leaching potential. Leaching of chemicals through soil is an important process which determines if a chemical will reach the ground water or remain at or near the soil surface. If a chemical reaches groundwater or remains at the soil surface, deleterious environmental and human health effects may arise due to plant and animal uptake and through the contamination of food and water supply.

This test was selected over the soil isotherm and soil column methods since it is the least expensive and most widely used technique for the screening of a chemical's leaching potential.

General Statement on Hazardous Solvents

Several of the tests contained in this standard require the use of solvents which are known or suspected to be hazardous. In a few cases the solvents are specified, e.g., benzene, and in other cases, where the tests specify a "solvent of choice," it is expected that benzene, or toluene, or other similar materials may be selected.

The Good Laboratory Practice Standards and other procedural specifications warn testing laboratories that such known or suspected hazardous materials should be used in these tests only in strict accordance with protective measures that will safeguard the laboratory personnel performing the tests.

Note.—Under Executive Order 12044, EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized." This regulation has been reviewed and it has been determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

(Sec. 4, Toxic Substances Control (TSCA), (90 Stat. 2006 (15 U.S.C. 2603)))

Dated: September 25, 1980.

Douglas M. Costle,

Administrator.

Therefore, it is proposed that 40 CFR Part 772 be amended by adding a new Subpart L to read as follows:

Subpart L—Physical, Chemical, and Environmental Persistence Characteristics

Sec.

772.122–1 Density/relative density.
772.122–2 Melting temperature.
772.122–3 Vapor pressure.
772.122–4 Octanol/water partition coefficient.
772.122–5 Soil thin-layer chromatography.

§ 772.122–1 Density/relative density.

(a) *Purpose.* This standard will develop data on density and relative density (specific gravity) of chemical substances and mixtures. EPA will use the data on density to evaluate the manner and extent that chemicals will be transported in the environment and the places where they will be deposited.

(b) *Definitions.* (1) "Apparent density" is the weight in air of a unit volume of a material. It differs from the density in that the buoyancy correction has not been applied, and normal gravity is assumed.

(2) "Apparent relative density" differs from the relative density in that the buoyancy corrections for the materials and the reference material have not been applied. For this test apparent relative density will be accepted as relative density.

(3) "Bulk density" of a material is the mass of material in a container divided by the volume of the container. In a loosely packed granular or powdery solid, a substantial fraction of the total space is occupied by gas that fills the interstices, and therefore bulk density is substantially less than the particle density. This test standard does not determine bulk density, it determines the particle which is the true density of the material.

(4) "Density" is the mass of a unit volume of a material. It is a function of temperature, hence the temperature at which it is measured should be specified. For a solid, it is the density of the impermeable portion rather than the bulk density.

(5) "Relative density" ("specific gravity") is the ratio of the density of a material to that of a reference material, each measured under specified conditions of temperature and pressure. For liquids the reference material is gas-free distilled water; for gases, it is dry air of normal carbon dioxide content.

(c) *Good laboratory practice.* The Good Laboratory Practice Standards for Physical, Chemical, Persistence, and Ecological Effects Testing in § 772.110–2 must be followed in performing this standard.

(d) *Conditions*—(1) *Apparatus.* The apparatus used for experimental tests must be of a type appropriate for the measurement technique being used, and must meet the following specific standards: Thermometers must conform to specifications as specified in the standard density measurement technique selected, and shall have a calibration traceable to the National Bureau of Standards. Other apparatus must conform to specifications of the protocol selected according to paragraph (e) of this section.

(2) *Materials.* The following materials must be available:

(i) Density reference substances as required by the technique, for calibrating the density-measurement apparatus and for comparative density measurements, selected from or in addition to the following list, and prepared according to the recommendation of the technique used in Table 1 under paragraph (e)(1)(i) of this section: gas-free distilled or demineralized water, mercury, standardized glass, cyclohexane, or toluene.

(ii) Comparison gases, as required by the technique, for relative density measurements of gases, or for displacement by solids. Suggested comparison gases are helium or dry air.

(iii) Immersion liquids as required by the technique and by the substance to be tested. Suggested immersion liquids are: water, kerosine, glycerine, ethylene glycol, tetrahydronaphthalene alpha-bromonaphthalene, sym-tetra-bromoethane, methylene iodide, benzene, toluene, ethyl-benzene, *o*-, *m*-, *p*-xylene, styrene, cyclohexane, or isopropyl salicylate.

(3) *Temperature of test.* (i) The density or relative density of the material must be determined at 25°C (298.15 K), except as allowed in paragraph (d)(3)(ii) or (iii), of this section.

(ii) If the material is an industrial material of a class for which engineering standards for measurement have been set at 15°C, the density may be measured at 15°C (288.15 K).

(iii) If the material belongs to a class of chemicals for which international measurement standards have been set at 20°C, the density may be determined at 20°C (293.15 K).

(e) *Procedures*—(1) *Selection of technique.* (i) Determine density or relative density using the appropriate technique, as specified below, selected from the techniques listed in Table 1 in this paragraph (e)(1)(i) and using the detailed techniques standardized for that procedure by one of the standardizing bodies identified in the following Table 1:

BILLING CODE 6560-31-M

TABLE 1-STANDARD DENSITY—MEASUREMENT TECHNIQUES REFERENCED IN THIS STANDARD

TECHNIQUE		CLASS OF SUBSTANCE			STANDARDIZING BODY AND IDENTIFICATION NUMBER		
		GAS	LIQUID	SOLID	ANSI/ASTM[1,2]	BSI	CIPAC
Ideal Gas Calculation		X					
Gas Density Balance		X			D 1070-73 (1979) [26]		
Hydrometer[6]			X		D 1298-67 (1977) [40][3] D 1657-64 (1976) [23] D 891-59 (1976) [29]	4714	MT3
Hydrostatic[7] Displacement			X	Chunks	D 792-66 (1979) [35] C 830-79 [17] D 891-59 (1976) [29] C 693-74[4] [17]		
Sink-Float Comparator				Chunks	C 729-75 [17]		
Pycnometer-Narrow-Mouth	Sprengel-Ostwald[6]		X				
	Lipkin Bicapillary[6]		X		D 941-55 (1978) [23][5] D 1481-62 (1976) [23, 40] D 3505-78 [29]	4699	MT3
	Bingham		X		D 891-59 (1976) [29] D 1217-54 (1976) [23] D 1480-62 (1976) [23]		
Pycnometer-Wide-Mouth	Volumetric Flask		X	Powder Crystals Chunks	D 153-54 (1975) [28] D 1076-79 [37]		
	Thermometer Stoppered		X	Powder Crystals Chunks	C 135-66 (1976) [17] D 792-66 (1979) [35]		
	Capillary Stopper[6]		X	Powder Crystals Chunks	D 1076-79 [37] D 153-54 (1975) [28] D 1817-66 (1972) [37] D 792-66 (1979) [35] D 891-59 (1976) [29]	5093	MT3
	Johnson and Adams		X	Powder Crystals Chunks			
Gas Comparison Pycnometer				Powder	C 604-79 [17]		

[1] Unless otherwise specified, these are joint standards.

[2] In brackets by ASTM Test Standard number is the volume number in which the standard appeared in the 1979 or 1980 Annual Book of ASTM Standards. Numbers in parentheses indicate the year of last reapproval.

[3] Adopted by American Petroleum Institute as API Standard No. 2547 and by the Institute of Petroleum as IP Standard No. 160.

[4] ASTM only

[5] Adopted by the General Services Administration as Method 402, Federal Test Method Standard 791b.

[6] DIN standard 51757 is acceptable.

[7] ISO Recommendation R 1183 is acceptable for plastics.

BILLING CODE 6560-31-C

Code to Standardizing Bodies in Table 1

ANSI—American National Standards Institute.
ASTM—American Society for Testing and Materials.
BSI—British Standards Institution.
IP—Institute of Petroleum.
CIPAC—Collaborative International Pesticides Analytical Council.
DIN—Das Ist Norm (earlier Deutsche Industrienormen).
API—American Petroleum Institute.
ISO—International Organization for Standardization.

The test standards in Table 1 of paragraph (e)(i)(i) of this section are incorporated by reference. Standards are available for purchase as follows:

ANSI, BSI, ISO, and DIN standards are available from: Sales Department, American National Standards Institute, 1430 Broadway, New York, NY 10018.

ASTM standards are available from: American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103.

API standards are available from: American Petroleum Institute, 2101 L Street NW., Washington, DC 20037.

IP standards are found in "Methods for Analysis and Testing" 38th Annual Edition, 1979. IP Standards for Petroleum and its Products. Part 1, Volume 1, which is available from Hayden and Son, Ltd., Spectrum House, Alderton Cres., London NW4 3XX U.K.

CIPAC standards are found in Raw GR, edition 1970, CIPAC Handbook, Volume 1. Analysis of Technical and Formulated Pesticides, published by the Collaborative International Pesticides Analytical Council Ltd., which is available for purchase from National Agricultural Chemicals Association, 1155 Fifteenth Street, NW., Washington, DC 20005.

The test standards are also available for inspection at the Office of the Federal Register, Information Center, Room 8301, 1100 L St., NW., Washington, DC 20408.

(ii) The technique to be used shall be selected on the basis of physical characteristics of the material to be tested as outlined in paragraphs (e)(1)(ii)(A) through (G) of this section and in Table 2 under paragraph (e)(1)(ii)(G) of this section.

(A) For a gas or a high volatility liquid, by the criterion in Table 2 in paragraph (e)(1)(ii)(G) of this section, the density and the relative density of the gas phase must be calculated by the ideal gas law as described in paragraph (e)(4)(ii) of this section, or

(B) At the option of the sponsor, the real gas density and relative density may be determined by the gas-density-balance technique in Table 1 under paragraph (e)(1)(i) of this section.

(C) For a high volatility liquid by the criterion in Table 2 under paragraph (e)(1)(ii)(G) of this section, the density or relative density must be determined by the hydrometer technique, or by the narrow-mouth pycnometer technique. For this class of liquid, the pycnometer capillary openings must have a cover to prevent evaporation.

(D) For a low volatility liquid of low viscosity by the criteria in Table 2 under paragraph (e)(1)(ii)(G) of this section, the density or relative density must be determined by the hydrometer technique, by the hydrostatic displacement technique, by the narrow-mouth pycnometer technique, or by the wide-mouth pycnometer technique. If the vapor pressure of liquid exceeds 15 kPa (0.15 atm), precautions must be taken to prevent excessive vaporization in carrying out these techniques.

(E) For a low volatility liquid of high viscosity, the density or relative density must be determined by the hydrometer technique, by the hydrostatic displacement technique, or by the wide-mouth pycnometer technique.

(F) For a solid in chunks or pieces the density or relative density must be determined by the hydrostatic displacement technique, by the sink-float comparator technique, or by the wide-mouth pycnometer technique. If the material is soluble in water or is not wetted by water, the immersion liquid must not be water, but must be another appropriate liquid in which the material is not soluble; in paragraph (d)(2)(iii) of this section.

(G) For a solid powder or small crystals, the density or relative density must be determined by the wide-mouth pycnometer technique or by the gas-comparison pycnometer technique. If the material is soluble in water or is not wetted by the water the immersion liquid used in the wide-mouth pycnometer technique must not be water but must be another appropriate liquid in which the material is not soluble; in paragraph (d)(2)(iii) of this section.

TABLE 2-PHYSICAL CHARACTERISTICS OF THE TEST MATERIAL FOR USE IN SELECTION OF MEASUREMENT TECHNIQUE

PHYSICAL STATE	CHARACTERIZING PARAMETER	DESCRIPTION AND APPROXIMATE LIMITS
Gas	Ideality	Ideal Gas
		Non-Ideal Gas
Liquid	Volatility[1]	Low Volatility p^o (25°C) < 80 kPa (0.8 atm)
		High Volatility p^o (25°C) > 15 kPa (0.15 atm)
	Viscosity[2]	Low Viscosity η (25°C) < 400 cm^2s^{-1}
		High Viscosity η (25°C) > 15 cm^2s^{-1}
Solid	Particle Size	Powder
		Small Crystals
		Chunks or Pieces
	Interfacial Tension	Wetted by Water
		Not Wetted by Water
	Solubility in Water	Soluble (> 1 Percent)
		Insoluble (< 1 Percent)

[1] p^o is the vapor pressure of the liquid. There is a range of vapor pressures, 0.15 to 80 kPa, in which a liquid may be treated as either a low-volatility liquid or a high volatility liquid.

[2] η is the kinematic viscosity. There is a range of viscosities, 15 to 400 cm^2s^{-1}, in which a liquid may be treated as either a low-viscosity liquid or a high-viscosity liquid.

(2) *Calibration.* For any technique other than the calculation of ideal gas density, the instrument used must be calibrated using a reference substance of known density as recommended in paragraph (d)(2)(i) or (g)(2)(ii) of this section.

(3) *Conduct.* Replicate measurements shall be made and averaged as prescribed in the description of the technique as referenced in Table 1 in paragraph (e)(1)(i) of this section.

(4) *Calculation.* (i) Except for the calculation of ideal-gas density, calculate density or relative density as prescribed in the description of the technique.

(ii) For calculation of ideal gas density and relative density, use the procedure given in paragraph (e)(4)(ii) (A) through (C) of this section.

(A) Calculate the molecular weight M, from the molecular formula and the relative atomic weights of the elements.

(B) Calculate the ideal gas density, ρ, in kg m^{-3}, at a temperature of 25°C (T=298.15 K) and a pressure of 101.325 kPa (p=1 atm) using the formula:

Equation 1

ρ (25°C, 1 atm)/ kg m^{-3}=101.325M/(8.3143×298.15) =0.040875M,

for which M was determined in paragraph (e)(4)(ii)(A) of this section.

(C) Calculate the relative density $d_{25/25C}$ with respect to air from the formula:

Equation 2

$d_{25/25C}$=M/28.964,

in which M was determined in paragraph (e)(4)(ii)(A) of this section.

(f) *Reporting.* (1) Report information required in the Good Laboratory Practice Standards under § 772.110–2(h).

(2) Report the physical characteristics of the material using descriptors from Table 2 in paragraph (e)(1)(ii)(G) of this section.

(3) Report measurement of density or relative density at a single temperature, and in the case of gases at a single pressure. The measurement must be at one of the temperatures specified in paragraph (d)(3) of this section.

(i) Report the density ρ of gases in kg m^{-3} and of liquids and solids in kg m^{-3} and report the temperature at which it was determined, or

(ii) Report the relative density, $d_t°_C$ in which t refers to the temperature of the material and of the reference substance (water or air) in °C. Report only relative densities in which the temperatures of the two materials are the same.

Identify the reference substance

(4) Report the technique used and identify the standard description of the technique from Table 1 under paragraph (e)(1)(i) of this section.

(5) Report the calibration substance used and, if relevant, the immersion substance used.

(6) Report the range of replicate measurements on the samples tested.

(7) If the material is variable in composition or has a variable density because of processing procedures, state the range of densities that conform to the specification of the material.

§ 772.122–2 Melting temperature.

(a) *Purpose.* This standard is to determine values of (normal) melting temperature of chemical substances and mixtures. EPA will use the data obtained to assess the potential for movement of materials in the environment and in evaluation of possible health and environmental effects.

(b) *Definitions.* (1) "Cooling curve melting temperature" is the temperature at which a melted material first shows a minimum rate of temperature change as it solidifies when allowed to cool under prescribed conditions.

(2) "Congealing temperature" is the temperature at which a wax ceases to flow when allowed to cool under prescribed conditions.

(3) "Drop melting temperature" is the temperature at which a wax becomes sufficiently fluid to drop from the thermometer used in making the determination under prescribed conditions.

(4) "Final melting temperature" is the temperature at which the last sample crystal disappears into the melt.

(5) "Initial melting temperature" is the temperature at which positive evidence of formation of liquid occurs; it is not a preliminary contraction, sintering, or darkening but occurs well before the formation of a meniscus.

(6) "Normal melting temperature" is the temperature at which the solid and liquid forms of a chemical substance are in equilibrium under an external pressure of one atmosphere. Normal melting temperature is commonly called "melting point."

(7) "Pour point" is the lowest temperature at which an oil is observed to flow when cooled under prescribed conditions.

(c) *Good laboratory practice.* The Good Laboratory Practice Standards for Physical, Chemical, Persistence, and Ecological Effects Testing in § 772.110–2 must be followed in performing this standard.

(d) *Conditions*—(1) *Laboratory apparatus.* (i) Thermometers used for this test must be of appropriate temperature range and meet specifications cited in the selected standard technique referenced in Table 1 under paragraph (e)(3)(iv) of this section with subdivisions of 1°C or smaller, and be capable of being read to 0.25°C. The thermometer must have a calibration traceable to the National Bureau of Standards.

(ii) The melting temperature apparatus must be of the type specified for use with the appropriate standard technique referenced in Table 1 under paragraph (e)(3)(iv) of this section or other acceptable technique. Equipment must meet the specifications in that technique, together with specified auxiliary instruments referenced in the same technique.

(2) Reference materials of known melting temperatures must be available for calibration of apparatus and verification of procedures. These are to be of a purified grade with melting temperature certified by the supplier. Reference materials include but are not limited to:

Benzene, 6°C.
L-Menthol, (42–43)°C.
Azobenzene, (68±1)°C.
Hydroxyquinoline, (75–76)°C.
Naphthalene, (80±0.5)°C.
Acetanilide, (113–114)°C.
Benzoic Acid, (122±1)°C.
Succinic Acid, (189–190)°C.
Phenolphthalein, (261–262)°C.

A list of substances for which the melting temperature is recommended as a thermometric fixed point is given by IUPAC (1979) in the 1979, International Union of Pure and Applied Chemistry Catalog of Reference Materials from National Laboratories. It is in the 1976 International Union of Pure and Applied Chemistry "Physicochemical Measurements: Catalog of reference Materials from National Laboratories" which is incorporated by reference. This list appeared in 1976 in Pure and Applied Chemistry, Vol. *48,* pages 503–515. It is for sale from Pergamon Press Inc., Maxwell House, Fairview Park, Elmsford, NY 10523. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L St., NW., Washington, DC 20408. Many of these substances can be obtained from a standardizing laboratory with a certified value of melting and freezing temperature.

(e) *Procedures.* (1) The test must be performed by a visual technique, in

which the transition between solid and liquid is observed.

(2) A preliminary examination of the material must be made to determine:

(i) Whether the material is sharply melting or passes through an extended softening interval.

(ii) Whether the material decomposes on melting.

(iii) Whether the material oxidizes or undergoes other reactions in air at or below the melting temperature.

(iv) Whether the material volatilizes rapidly so as to require special handling.

(v) Whether the material melts below −20°C or above +250°C.

(3) Since chemicals vary in their physical form and properties, several techniques, have to be available to accommodate these differences. Therefore, the test shall be performed by one of the standard techniques listed below and (or) in Table 1 under paragraph (e)(3)(iv) of this section, as provided below, except as provided in paragraph (e)(4) of this section.

(i) If the sample passes through an extended softening interval, use the drop melting point technique, the pour point technique, or the cooling curve technique.

(ii) If the material decomposes on melting use the Fisher-Johns technique, the microscope hot stage technique, or the Kofler hot bench technique.

(iii) If the material reacts or volatilizes use a suitable sealed tube technique.

(iv) For materials not exhibiting special properties listed in paragraph (e)(3) (i), (ii), or (iii) of this section, use the Thiele tube, cooling curve, Fisher-Johns, microscope hot stage, or Kofler hot bench technique as specified in this Table 1.

BILLING CODE 6560-31-M

TABLE 1-STANDARD MELTING TEMPERATURE TECHNIQUES REFERENCED IN THIS STANDARD

TECHNIQUE	STANDARDIZING BODY[1]					
	ANSI/ASTM[2,3]	TAPPI	FTS[4]	BSI	IP	CIPAC
Thiele Tube	E 324-79 [30] D 1519-68[5] (1974) [37]					MT2
Cooling Curve	D 87-77 [23] [20]	T630-os-71	791B#1402.5	4695	55	MT1
Fisher-Johns	D 789-78a [36] D 1457-78 [36] D 2116-79 [36] D 2133-78 [36]					
Microscope Hot Stage	D 2117-64 (1978) [35]					
Kofler Hot Bench	D 3451-76 [27]					
Drop Melting Point	D 127-63 (1977) [23] [20]	T634-os-70	791B#1401.4	5090	133	
Pour Point	D 97-66 (1978) [23] [40]		791B#201.9	4452	15	
Congealling Point	D 938-71 (1976) [23]			5088	76	

[1]Names of standardizing bodies are given in text.
[2]Joint standard unless otherwise specified.
[3]In brackets by ASTM Test Standard number is the volume number in which the standard appeared in the 1979 or 1980 Annual Book of ASTM Standards. Numbers in parentheses indicate the year of last reapproval.
[4]Identical to ANSI/ASTM standard.
[5]ASTM only.

BILLING CODE 6560-31-C

Code to Standardizing Bodies in Table 1

ANSI—American National Standards Institute.
ASTM—American Society for Testing and Materials.
TAPPI—Technical Association for the Pulp and Paper Industry.
FTS—Federal Test Standards.
BSI—British Standards Institution.
IP—Institute of Petroleum.
CIPAC—Collaborative International Pesticides Analytical Council.

The test standards in this Table 1 are incorporated by reference. Standards are available for purchase as follows:

ANSI and BSI standards are available for puchase from: Sales Department, American National Standards Institute, 1430 Broadway, New York, NY 10018.

ASTM standards are available for purchase from : American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103.

TAPPI standards are available for purchase from: TAPPI Press, Technical Association of the Pulp and Paper Industry, One Dunwoody Park, Atlanta GA 30338.

FTS Standards are identical to the corresponding ASTM standards and should be obtained from the same source as ASTM standards.

IP standards are found in "Methods for Analysis and Testing," 38th Annual Edition, IP Standards for Petroleum and its Products, Part 1, Volume 1, which is available for purchase from: Hayden and Son, Ltd., Spectrum House, Alberton Cres., London NW4 3XX, United Kingdom.

CIPAC standards are found in Raw, GR, editor. 1970. CIPAC Handbook, Volume 1. Analysis of Technical and Formulated Pesticides, published by the Collaborative International Pesticides, Analytical Council Ltd., which is available for purchase from: National Agricultural Chemical Association, 1155 Fifteenth Street, NW., Washington, DC 20005.

The test standards are also available for inspection at the Office of the Federal Register, Information Center, Room 8301, 1100 L St. NW., Washington, DC 20408.

(4) If the material is subjected to a study of its melting temperature by a more accurate procedure than those listed in Table 1, the procedure used will be accepted in lieu of the procedure of paragraph (e)(3) of this section, provided that the preliminary examination given in paragraph (e)(2) of this section has been completed and does not contraindicate the substitute procedure.

(f) *Reporting.* In addition to reporting required in § 772.110–2(h) of Good Laboratory Practice Standards for Physical, Chemical, Persistence, and Ecological Effects Testing, report the following:

(1) Report the results of the preliminary examination by giving the temperature range, where applicable, at which the sample:

(i) Decomposes before melting.

(ii) Decomposes on melting.

(iii) Oxidizes (or other reaction) in air on melting.

(iv) Softens over a range of temperatures.

(v) Melts sharply.

(vi) Was examined and did not melt. If the chemical decomposes as a solid or if it sublimes, melting temperature data will not be required. If decomposition occurs, report the temperature at which it occurs. If sublimation occurs, report the maximum temperature to which it was tested.

(2) Report the technique used in the melting temperature determination and the reference material used.

(3) If the technique is selected in accordance with paragraph (e)(3)(iii) or (4) of this section and is different from any listed in Table 1 in paragraph (e)(3)(iv) of this section:

(i) Briefly, describe it, cite a reference to the technique, and provide justification that it is more accurate than techniques listed in Table 1 under paragraph (e)(3)(iv) of this section.

(ii) Report the initial melting tempera ture, the final melting temperature, and the limits of uncertainty at the 95 percent confidence level.

(4) If the Thiele tube technique is used report:

(i) The initial melting temperature and the final melting temperature to the nearest 0.1°C and the range of replicate measurements made, adjusted for any errors in the melting temperature of the reference material.

(ii) The identity, the initial melting temperature, and the final melting temperature found for the standard reference material used to verify the performance of the instrument.

(iii) The amount of any adjustment made to correct for errors in the melting temperature of the standard.

(5) If the cooling curve technique is used:

(i) Record the melting temperature thermometer reading every 15 seconds to the nearest estimated 0.05°C and identify and report the plateau at which the first five consecutive readings agree within 0.1°C. Report the average of the first five consecutive readings of the identified plateau, which agree within 0.1°C. Correct this average for error in the thermometer scale.

(ii) Report the result to the nearest 0.05°C as "cooling curve melting temperature."

(iii) If no plateau is observed within the stipulated temperature limitations below a temperature at which the material has solidified, the test is discontinued and the method is judged not applicable to the material.

(iv) Report the range of cooling curve melting temperatures that conforms to the specification of the material under test.

(6) If the pour point technique is used:

(i) Record the reading of the thermometer when a point is reached at which the material in the test jar shows no movement when the jar is held in a horizontal position for 5.0 seconds. Add 3°C to this temperature to obtain the pour point temperature.

(ii) For those samples (e.g., nondistillate fuel oil) where the prescribed procedure gives the upper (maximum) pour point, report the lower pour point obtained after heating the sample to 104°C as prescribed.

(iii) Record all pour points to the nearest 1°C.

(iv) Report the limits of pour point or of upper pour point and lower pour point that conform to the specification of the material under test.

(7) If the drop melting temperature technique is used:

(i) Report the average of the two determinations of the temperature at which the first drop falls from the thermometer as the drop melting temperature of the sample of material under test, and also report the range of the two determinations.

(ii) Report the limits of drop melting temperature that conform to the specification of the material under test.

(8) If the Fisher-Johns technique is used for ANSI/ASTM Standards D 789 and D 2133 as listed in Table 1 under paragraph (e)(3)(iv) of this section:

(i) Report the melting temperature to the nearest 0.5°C observed as the temperature at which the material no longer supports the cover glass and the glass begins to sink into the oil, as observed by watching for movement of the oil meniscus. The thermometer with its bulb imbedded immediately below hot stage indicates the melting temperature.

(ii) Report the range of melting temperature that conforms to the specification of the material under test.

(9) If the microscope hot stage technique is used:

(i) Report as the normal melting temperature the average of the results of two determinations and range of values observed when all double refraction disappears, leaving a totally dark microscope field.

(ii) If the material is a polymer report the range of melting temperature that

conforms to the specification of the material under test.

(10) If the Kofler hot bench technique is used:

(i) For sharply melting materials, record the placement of the temperature-indication pointer at the point of division between solid and liquid on the heating bar.

(ii) For polymeric materials record the placement of the temperature-indicating pointer at the location at which particles adhere to the heating bar when lightly brushed.

(iii) Report the average of duplicate determinations to the nearest 1°C as the normal melting temperature of the sample tested, and report the range of the duplicate determinations.

(iv) If the material is a polymer, report the range of melting temperatures that conforms to the specification for the material under test.

(11) If the congealing point technique is used:

(i) Report to the nearest 0.25°C as the congealing temperature the average of two determinations that agree within 1°C or the average of three determinations for which the range exceeds 1°C.

(ii) Report the range of congealing temperatures that conforms to the specification of the material under test.

§ 772.122–3 Vapor pressure.

(a) *Purpose.* The standard in this subpart is designed to develop values of vapor pressure, at environmentally relevant temperatures, of chemical substances. The EPA will use the data to evaluate transport in the environment.

(b) *Definitions.* (1) "Desorption efficiency" of a particular compound applied to a sorbent and subsequently extracted with a solvent is the weight of the compound which can be recovered from the sorbent divided by the weight of the compound originally sorbed.

(2) "Pascal" (Pa) is an international unit of vapor pressure and is defined as newtons per square meter (N/m^2). A Newton is the force necessary to give acceleration of one meter per second squared to one kilogram of mass.

(3) The "torr" is a unit of pressure defined as equal to 133.3 pascals or 1 mm Hg at 0°C.

(4) The "vapor pressure" is the pressure at which a liquid or solid is in equilibrium with its vapor at a given temperature.

(5) "Volatilization" is the loss of a substance to the air from a surface or from solution by evaporation.

(c) *Good laboratory practice.* The Good Laboratory Practice Standards for Physical, Chemical, Persistence, and Ecological Effects Testing, in § 772.110–2, must be followed in performing this standard.

(d) *Conditions.* (1) The apparatus used for the test procedures must be of a type appropriate for the measurements described in paragraphs (e) and (g) of this section.

(2) The tests must be performed under conditions of normal laboratory room temperatures.

(e) *Procedures.* The vapor pressure of compounds must be determined by one of the following procedures.

(1) *Isoteniscope procedure.* The isoteniscope procedure described as ANSI/ASTM Method D 2879–75 is applicable for the measurement of vapor pressures of liquids with vapor pressures of 0.1 to 100 kilopascals (kPa) (0.75 to 750 torr). ANSI/ASTM D 2879–75, "Standard Test Method for Vapor Pressure-Temperature Relationships And Initial Decomposition Temperature of Liquids by Isoteniscope", is incorporated by reference. It is for sale from the American Society for Testing and Materials, 1916 Race Street, Philadelphia Pa. 19103. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street NW, Washington, D.C. 20408. The isoteniscope method involves placing a liquid sample in a thermostated bulb (the isoteniscope) connected to a manometer and a vacuum pump. Dissolved and entrained gases are removed from the sample in the isoteniscope by heating the sample at reduced pressure. The vapor pressure of the sample at selected temperatures is determined by balancing the pressure due to the vapor of the sample against a known pressure of an inert gas. The vapor pressure of the test compound must be determined in triplicate at 25 ± 0.5°C and at any other temperatures (± 0.5°) specified in a Test Rule. Additional vapor pressure measurements must be made at appropriate temperatures, as necessary, to assure that there is no need for further degassing, as described in the ASTM method.

(2) *Gas saturation procedure.* The gas saturation procedure, described in paragraph (g) of this section, is applicable for solids and liquids with vapor pressures at ambient temperatures of 10^{-5} Pa to 1 kPa (7.5×10^{-8} torr to 7.5 torr).

(f) *Reporting.* (1) Report information required in § 772.110–2 (h) of Good Laboratory Practice Standards.

(2) The triplicate calculated vapor pressures for the test material at each test temperature and the average calculated vapor pressure at each temperature must be reported.

(3) A description of analytical methods used to analyze for the test material and all analytical results must be reported.

(4) For the isoteniscope procedure, the plot of log p vs the reciprocal of the temperature in K, developed during the degassing step and showing linearity in the region of 298.15 K (25°C) and any other required test temperatures, must be included.

(5) For the gas saturation procedure, the data must include calculations of vapor pressure at three or more gas flow rates at each test temperature, showing no dependence on flow rate. The data also must include a description of sorbents and solvents employed and the desorption efficiency calculations.

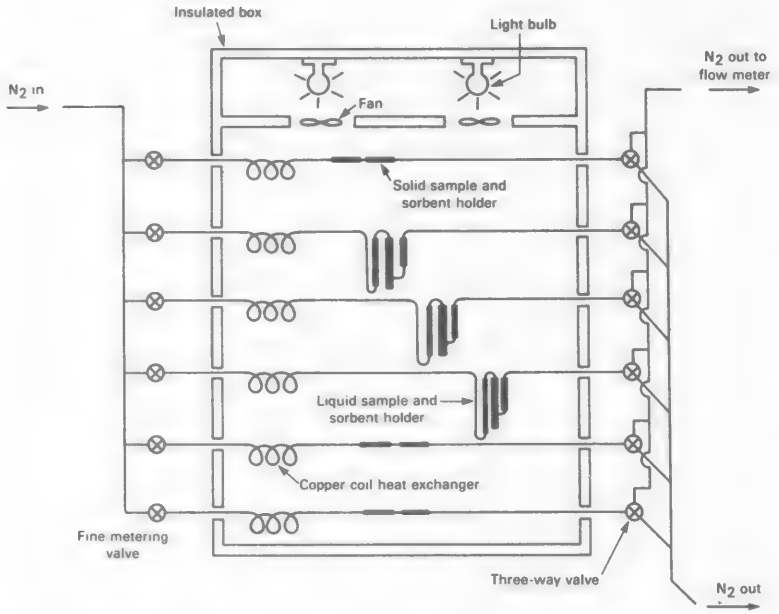
(6) The average calculated vapor pressure at each temperature must include the calculated standard deviation.

(7) A description of any difficulties experienced or any other pertinent information should be provided.

(g) *Gas saturation procedure for vapor pressure.* The gas saturation procedure is based on methodology currently being developed by SRI International under contract to the Environmental Protection Agency (EPA Contract No. 68–01–5117).

(1) The test procedures require the use of a constant-temperature box as in the following Figure 1.

FIGURE 1 - SCHEMATIC DIAGRAM OF VAPOR SATURATION APPARATUS



The insulated box, containing sample holders, may be of any suitable size and shape. The sketch in Figure 1 shows a box containing three solid sample holders and three liquid sample holders, which allows for the triplicate analysis of either a solid or liquid sample. Temperatures within the box must be controllable to ±0.5° or better. Nitrogen gas, split into six streams and controlled by fine needle valves (approximately 0.79 mm orifice), flows into the box via 3.8 mm (0.125 in.) i.d. copper tubing. After temperature equilibration, the gas flows through the sample and the sorbent trap and exits from the box. The flow rate of the effluent carrier gas is measured at room temperature with a bubble meter or other suitable device. The flow rate must be checked frequently during the experiment to assure that there is an accurate value for the total volume of carrier gas. The flow rate is used to calculate the total volume (at room temperature) of gas that has passed through the sample and sorbent (vol/time x time= volume). The vapor pressure of the test substance can be calculated from the total gas volume and the mass of sample vaporized. If v is the volume of gas that transported mass w of the vaporized test material having a molecular weight M, and if p is the equilibrium vapor pressure of the sample at temperature T, then p is calculated by the equation:

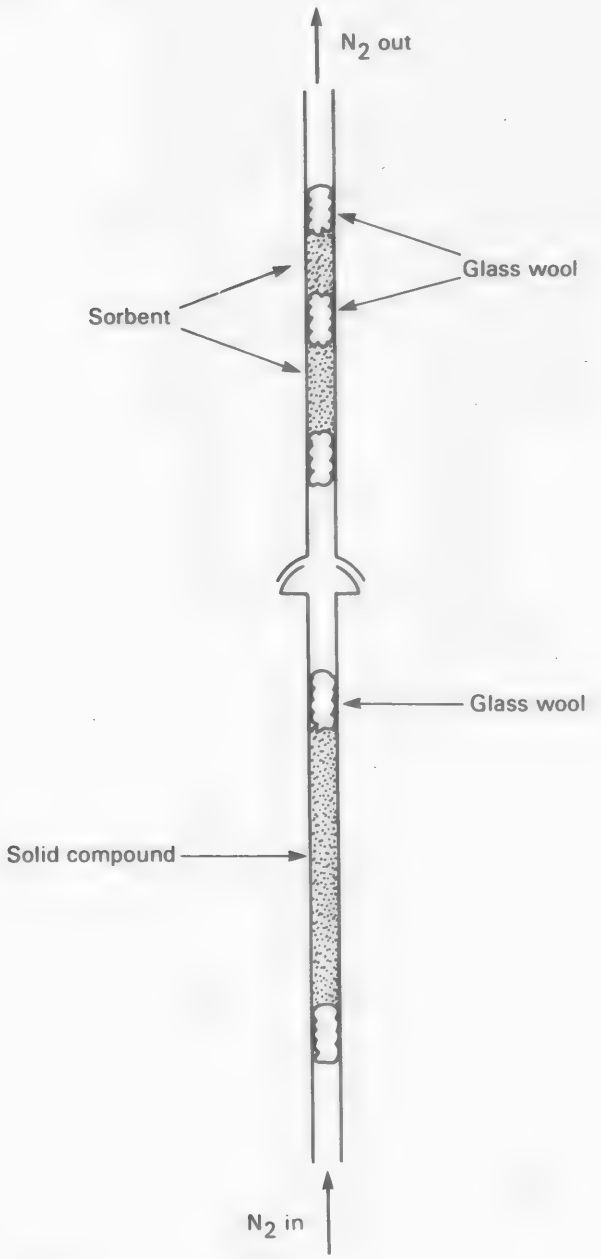
$$p = (w/M)(RT/v)$$

In the equation, R is the gas constant (8.31 Pa $m^3 mol^{-1} K^{-1}$). The pressure is expressed in pascals (Pa), the volume in cubic meters (m^3), mass in grams and T in kelvins (K). $T = 273.15 + t$, if t is measured in degrees Celsius (°C).

(2) Solid samples are loaded into 5-mm i.d. glass tubing between glass wool plugs. The following Figure 2 is a drawing of a sample holder and absorber system.

BILLING CODE 6560-31-M

FIGURE 2 - SOLID COMPOUND SAMPLING SYSTEM



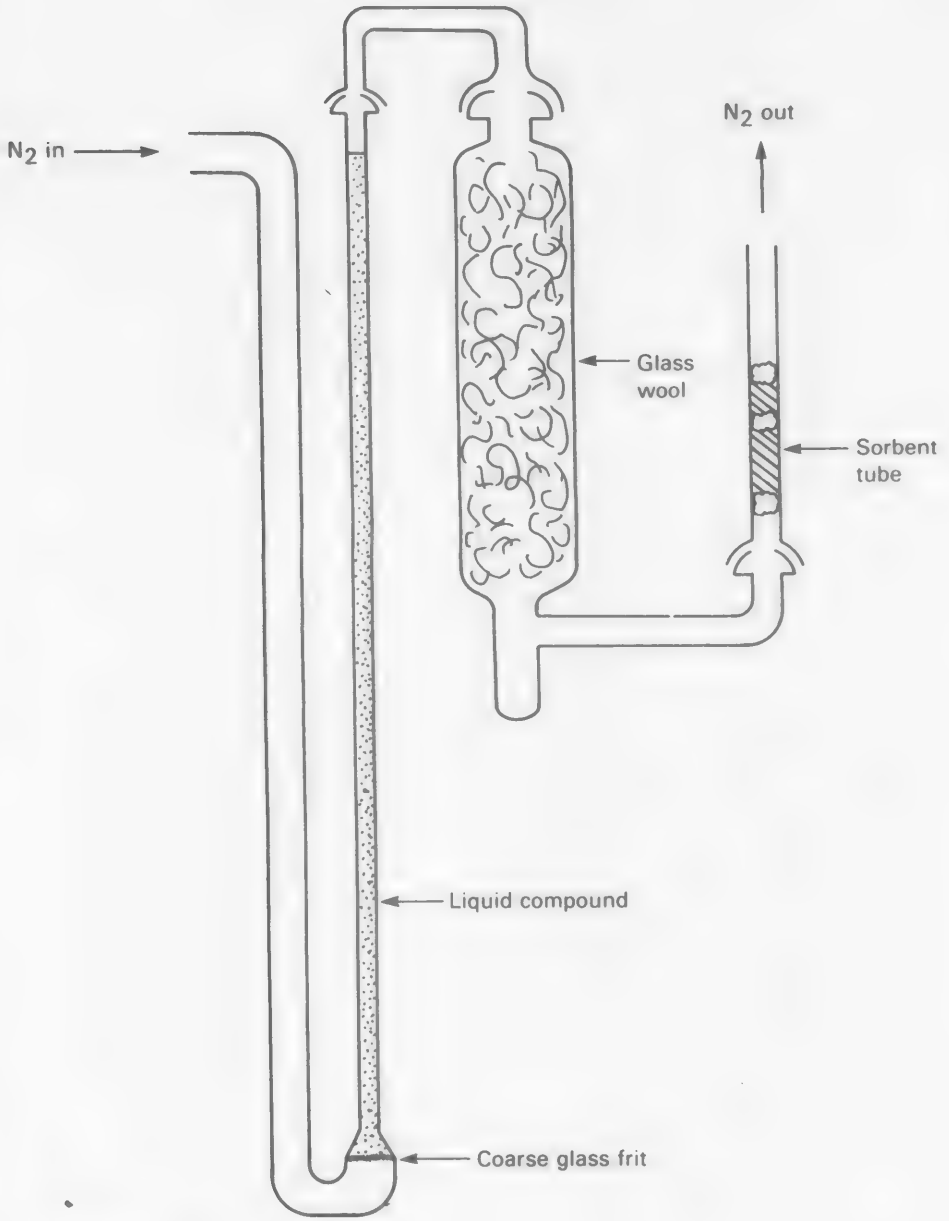
BILLING CODE 6560-31-C

Sample length is about 50 mm. The sample tube is connected by a ground-glass ball-and-socket joint to a similar tube containing the sorbent. The sorbent tube contains two sections of sorbent material (front and backup) separated by glass wool. The sections are approximately 15 mm and 10 mm long, respectively. The backup section is used to check for compound release from the front section.

(3) Liquid samples are contained in a holder as shown in the following Figure 3:

BILLING CODE 6560-31-M

FIGURE 3 — LIQUID COMPOUND SAMPLING SYSTEM



BILLING CODE 6560-31-C

Incoming nitrogen gas (containing no interfering impurities) passes through a coarse frit and bubbles through a 38 cm column of liquid sample. The stream passes through a glass wool column to trap aerosols and then through a sorbent tube, as described above. The pressure drops across the glass wool column and the sorbent tube are negligible.

(4) With both solid and liquid samples, at the end of the sampling time, the front and backup sorbent sections are analyzed separately. The compound on each section is desorbed by adding the sorbent from that section to 1.0 ml of desorption solvent in a small vial and allowing the mixture to stand at a suitable temperature until no more test compound desorbs. The desorption solvent must contain no impurities which would interfere with the analytical method of choice. The resulting solutions are analyzed quantitatively by a suitable analytical method to determine the weight of sample desorbed from each section. The choice of the analytical method, sorbent, and desorption solvent is dictated by the nature of the test material. Commonly used sorbents include charcoal, Tenax GC, and XAD–2. The sorbent, desorption solvent, and analytical methods employed must be described in detail.

(5) The desorption efficiency must be measured for every combination of sample, sorbent, and solvent used. The desorption efficiency is determined by injecting a known mass of sample onto a sorbent and later desorbing it and analyzing for the mass recovered. For each combination of sample, sorbent, and solvent used, the determination must be made in triplicate at each of three concentrations. Desorption efficiency may vary with the concentration of the actual sample and it is important to measure the efficiency at or near the concentration of sample under gas saturation test procedure conditions.

(6) To assure that the gas is indeed saturated with test compound vapor, each compound must be sampled at three differing gas flow rates. Appropriate flow rates will depend on the test compound and test temperature. If the calculated vapor pressure shows no dependence on flow rate, then the gas is assumed to be saturated.

§ 772.122–4 Octanol/water partition coefficient

(a) *Purpose.* This standard is designed to develop values of octanol/water partition coefficient of chemical substances and mixtures. The EPA will use the numerical values of the octanol/water partition coefficient obtained to help assess environmental fate, health, and environmental effects of chemical substances.

(b) *Definition.* "Octanol/water partition coefficient" (K_{ow}) is defined as the equilibrium ratio of the molar concentrations of a chemical in n-octanol and water, in dilute solution. K_{ow} is a constant for a given chemical at a given temperature.

(c) *Good laboratory practice.* The Good Laboratory Practices Standards for Physical, Chemical, Persistence, and Ecological Effects Testing, in § 772.110–2, must be followed in performing this standard.

(d) *Conditions.*—(1) *Special laboratory equipment.*

(i) A thermostatic bath, or chamber, or room with a shaker and temperature control as specified in paragraph (d)(2) of this section.

(ii) An ultracentrifuge with temperature control as specified in paragraph (d)(2) of this section.

(iii) Stainless steel or glass centrifuge tubes with sealable caps. Special glass centrifuge tubes can be used up to approximately 12,000G, and stainless steel tubes can be used at higher G values.

(iv) A mechanical shaker.

(v) A Hach 2100 Turbidimeter (or an equivalent instrument).

(vi) A pH meter capable of resolving differences of 0.1 pH unit or less.

(2) *Temperature control.* The temperature of the water bath, or chamber, or room, and the ultracentrifuge must be controlled to (25 ± 1) °C.

(3) *Purity of solvents. n*-Octanol, purified as described in the test procedures under paragraph (g)(1)(i) of this section, and distilled or reagent grade water, i.e. ASTM Type II water or an equivalent grade must be used. ASTM Type II water is described in ASTM D 1193–77, "Standard Specification for Reagent Water", which Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street, NW, Washington, D.C. 20408.

(4) *Concentration of solute.* All experiments must be carried out at a concentration $C < 0.01M$ (Molar) in octanol and water and well below the solubility in either phase.

(5) *Equilibration time.* In general, 1 hour of gentle agitation is sufficient to reach equilibrium. For surfactants, at least 16 hours is required to reach equilibrium.

(6) *Octanol/water volume ratio.* The ratio of the volumes of the two liquids must be adjusted as appropriate for the relative solubility of the chemical in octanol and water. By adjusting the volumes, concentration errors (resulting from analytical errors) are minimized and errors resulting from dividing large numbers by small numbers are kept to a minimum.

(7) *Chemical analysis of the octanol and water phases.* In determining the K_{ow} value for any given solute, the octanol and water phases must be analyzed for the chemical. An analytical method should be selected which is most applicable to the analysis of the specific chemical. Chromatographic methods are preferable because of their compound specificity in analyzing the parent chemical without interference from impurities. Whenever practicable, the chosen analytical method should have a precision within ±5 percent.

(8) *Emulsification and ultracentrifugation.* Gentle shaking must be used to minimize the formation of emulsions. Ultracentrifugation is necessary to separate troublesome emulsions and to separate the octanol and water phases. Therefore, ultracentrifugation must be carried out at 25°C for 20 minutes in a temperature controlled ultracentrifuge. The acceleration (G) value required to break the emulsion and to achieve complete separation of the octanol and water phases can be determined by trial-and-error experimentation.

(9) *Equilibration vessel.* (i) If feasible, equilibration should be carried out in a centrifuge tube (stainless steel or glass) with a sealable cap. The centrifuge tubes must be almost completely full. In this way, partitioning with air will be minimized, especially for volatile chemicals, and the mixture will be completely mixed.

(ii) Very hydrophobic chemicals, with K_{ow} in the order of 10^4 to 10^6, require relatively large volumes of the aqueous phase. Hence, for these chemicals, equilibration must be carried out in a large ground-glass stoppered flask.

(10) *Speciation effects.* The octanol/water partition coefficient, K_{ow}, has been defined in paragraph (b) of this section. The mathematical statement of K_{ow} is:

Equation 1

$$K_{ow} = \frac{C_{octanol}}{C_{water}}$$

where C is the molar concentration of the solute in octanol and water at equilibrium at a given temperature.

(i) If the chemical does not associate or dissociate in octanol and water, then equation (1) must be used and K_{ow} must be determined at molar concentrations $C < 0.01M$ and $C_1 = 0.01C$.

(ii) If the chemical associates in octanol or water or in both liquids, then equation (1) must be used and K_{ow} must be determined at molar concentrations $C < 0.01M$, $C_1 = 0.1C$, $C_2 = 0.01C$, $C_3 = 0.001C$. . . . . When K_{ow} is constant at two molar concentrations differing by a factor of 10, then the effect of association has been minimized or eliminated.

(iii) If a molecule dissociates or associates in octanol and water, then equation (1) must be modified to take into account such speciation changes as ionization, aggregation, and hydration. For the special case where no association takes place in octanol and only dissociation takes place in water, equation (1) becomes:

Equation 2

$$K_{ow} = \frac{C_{octanol}}{(1 - \alpha_{water})(C_{water})}$$

where α represents the degree of dissociation in water. For chemicals which reversibly ionize or protonate (e.g., carboxylic acids, phenols, or anilines), equation (2) must be used with water buffered at pH 5.0, 7.0, and 9.0. Buffers described in the test procedures under paragraph (g)(1)(ii) of this section must be used.

(11) *Prerinsing of all transfer vessels.* All transfer vessels must be prerinsed with a portion of the equilorium aqueous phase prior to transfer for analysis.

(e) *Procedures.* The test conditions outlined in paragraph (d) of this section must be followed in carrying out all octanol/water partition coefficient experiments. Recommended procedures are given in the test procedures under paragraph (g) of this section.

(f) *Reporting.* In addition to the following requirements, information specified in § 772.110–2(h) of Good Laboratory Practice Standards must be reported. This test standard is designed to determine the octanol/water partition coefficient of the test chemical in the range 10 to 10^6. For chemicals outside this range, the octanol/water partition coefficient should be reported as $K_{ow} < 10$ or $K_{ow} > 10^6$ with no further quantification.

(1) *Specific analytical and recovery procedures.* (i) Provide a detailed description or reference for the analytical procedure used, including the calibration data and precision.

(ii) If extraction methods were used to separate the solute from the octanol and aqueous phases, provide a description of the extraction method and recovery data.

(iii) Report the experimental (G) value required to break the emulsion and to achieve complete separation of the octanol and water phases.

(2) *Test data.* For each individual determination, report the octanol/water partition coefficient at each concentration of the test substance, including the molar concentration of chemical in each phase [C_{oct} and C_{water}]. In addition, report the mean value of K_{ow}, and the standard deviation.

(g) *Test procedures*—(1) *Reagents and solutions.* (i) *Octanol and water.* Very pure *n*-Octanol can be obtained as follows: Wash pure *n*-octanol (minimum 98 percent pure) sequentially with 0.1N H_2SO_4, with 0.1N NaOH, then with distilled water until neutral. Dry the *n*-octanol with magnesium sulfate and distill twice in a good distillation column under reduced pressure [b.p. about 80°C at 0.27 kPa (2 torr)]. The octanol produced must be at least 99.9 percent pure, e.g., a grade equivalent to Fisher Scientific Co. No. A–402 "Certified Octanol-1". Distilled or reagent grade (ASTM Type II) water must be used.

(ii) *Buffer solutions.* Prepare buffer solutions using reagent grade chemicals in distilled or reagent grade water as follows:

pH 5.0—250 mL of 0.1M potassium hydrogen phthalate; 113 mL of 0.1M sodium hydroxide. Adjust final volume to 500 mL with reagent grade water.

pH 7.0—250 mL of 0.1M potassium dihydrogen phosphate; 145 mL of 0.1M sodium hydroxide. Adjust final volume to 500 mL with reagent grade water.

pH 9.0—250 mL of 0.075M borax; 69 mL of 0.1M HCl. Adjust final volume to 500 mL with reagent grade water.

Check the pH of each buffer solution with a pH meter at 25°C and adjust to pH 5.0, 7.0, or 9.0, if necessary.

(iii) *Presaturation of the solvents.* Before a partitioning experiment is carried out, prepare octanol saturated with water and water saturated with octanol. Add purified *n*-octanol to a large stock bottle and sufficient distilled water to saturate it. Shake the flask for 24 hours on a mechanical shaker. Then allow sufficient time for the mixture to stand so that the two phases separate. Repeat this procedure using another large stock bottle containing distilled water and sufficient octanol to saturate it. The desired quantities of the presaturated solvents can be taken from these stock bottles for each partition experiment.

(iv) *Preparation of test solution.* Prepare a solution of the test material in octranol at a molar concentration of 10^{-2} to 10^{-3}M.

(2) *Procedure.* (i) Add a small volume of the octanol test solution (1 to 5 mL) to a centrifuge tube with a sealable cap as described under paragraph (d)(9) of this section.

(ii) The volume of water required is variable, depending upon the amount of chemical required for chemical analysis. Generally, 20–40 mL of water should be sufficient. Add the required volume of water to the centrifuge tube as described under paragraph (d)(6) of this section. Make sure that the centrifuge tube is almost completely full. In this way, partitioning with air will be minimized. This is important, especially when determining K_{ow} for volatile chemicals.

(iii) Equilibrate the samples at 25°C in a constant temperature bath, or chamber, or room by gently shaking the centrifuge tube for 1 hour. Avoid vigorous shaking which may cause troublesome emulsions to form. For surfactants, a minimum of 16 hours of shaking is required as described in paragraph (d)(5) of this section.

(iv) Centrifuge the samples at 25°C for 20 minutes to break any emulsion and to separate the octanol and water phases. Evidence for breaking the emulsion and separation of the water and octanol phases can be obtained using a turbidimeter. The acceleration (G) value required to break the emulsion and to achieve complete separation of the octanol and water phases can be determined by trial-and-error experimentation.

(v) Sample the octanol and water phases as follows:

(A) Withdraw by pipet a known volume of the octanol phase (approximately 1/2 or less of the total octanol phase) and transfer to an analysis cell or diluting solvent. Before transferring the aliquot of the octanol phase, wipe the outside of the pipet with a paper tissue.

(B) Remove by pipet the remainder of the octanol phase including the interfacial layer and discard.

(C) Insert another clean pipet close to the bottom of the centrifuge tube and carefully withdraw a known volume of the aqueous phase. Wipe the bottom exterior part of the pipet with a tissue and discharge the aqueous sample directly into an analysis cell or extraction solvent. Do not allow the extraction solvent to contact the pipet stem.

(vi) Select an analytical method which is most applicable to the analysis of the specific chemical as described in paragraph (d)(7) of this section. Determine the concentration in the octanol and water phases. Express the concentration of the chemical in octanol and water in moles/liter (M).

(vii) Determine the partition coefficient in triplicate (Steps i through vii) at two concentrations of the test material $C < 0.01M$ and $C_1 = 0.1C$ as described in paragraph (d)(10)(i) of this section. If K_{ow} is not constant at C and C_1 then association effects should be considered. Therefore, follow steps i through vii at lower concentrations until K_{ow} is constant at two concentrations differing by a factor of 10 as described in paragraph (d)(10)(ii) of this section.

(viii) Very hydrophobic chemicals (with K_{ow} on the order of 10^4 to 10^6) require relatively large volumes of the aqueous phase as described in paragraph (d)(6) and (9)(ii) of this section. Hence, for very hydrophobic materials, equilibrate the octanol and water phases in a large ground-glass stoppered flask as described in step iii. For the final phase separation, transfer the two phase mixture to centrifuge tubes that have been prerinsed with some of the aqueous phase, centrifuge as described in step iv, withdraw aliquots from each centrifuge tube as described in step v, and recombine for analysis. Note: Prerinse all transfer tubes with the water phase. Complete steps vi and vii to determine K_{ow}

(ix) For materials which reversibly ionize or protonate, determine K_{ow} at pH 5.0, 7.0, and 9.0 as described in paragraph (d)(10) (ii) of this section. Follow steps i through vii using the buffered aqueous solutions described in paragraph (g)(1)(ii) of this section. Using the acid dissociation constant and the concentration of the chemical in the aqueous phase [C_{water}], the term α can be calculated. The concentration of undissociated chemical can be determined from α and C_{water}.

§ 772.122–5 Soil thin-layer chromatography.

(a) *Purpose.* This standard is designed to develop soil leaching data on chemical substances at an environmentally relevant temperature. The EPA will use these data to evaluate adsorption and desorption of chemicals in the environment.

(b) *Definitions.* (1) "Cation exchange capacity" (CEC) is the sum total of exchangeable cations that a soil can adsorb; expressed in milliequivalents per 100 grams or milliequivalents per gram of soil.

(2) "Particle size analysis" is the determination of the various amounts of the different particle sizes in a soil sample (i.e., sand, silt, clay) usually by sedimentation, sieving, micrometry or combinations of these methods. The names and size limits of these particles as widely used in the United States are:

Very coarse sand—2.0 to 1.0 mm dia
Coarse sand—1.0 to 0.5 mm
Medium sand—0.5 to 0.25 mm
Fine sand—0.25 to 0.125 mm
Very fine sand—0.125 to 0.062 mm
Silt—0.062 to 0.002 mm
Clay—<0.002 mm

(3) "R_f" is the furthest distance traveled by a test material on a thin-layer chromatography plate divided by the distance traveled by a solvent front (arbitrarily) set at 10.0 cm in soil TLC studies).

(4) "Soil" is the unconsolidated mineral material on the immediate surface of the earth that serves as a natural medium for the growth of land plants, and has been subjected to and influenced by various factors such as parent material, climate, macro- and microorganisms, topography, and time.

(5) "Soil aggregate" is the combination or arrangement of soil separates (sand, silt, clay) into secondary units. These units may be arranged in the profile in a distinctive characteristic pattern and can be classified on the basis of size, shape, and degree of distinctness into classes, types, and grades.

(6) "Soil classification" is the systematic arrangement of soils into groups or categories on the basis of their characteristics; broad groupings are made on the basis of general characteristics and subdivisions on the basis of more detailed differences in specific properties. The soil classification system used today in the United Stats is the 7th Approximation-Comprehensive System.

(7) "Soil horizon" is a layer of soil or soil material approximately parallel to the land surface and differing from adjacent layers in physical, chemical, and biological properties or characteristics such as color, structure, texture, consistency, kinds, and numbers of organisms present, degree of acidity or alkalinity, and various other properties.

(8) "Soil order" is the broadest category of soil classification based on general similarities of physical/chemical properties resulting from formation by similar general genetic processes.

(9) "Soil organic matter" is the organic fraction of the soil; it includes plant and animal residues at various stages of decomposition, cells and tissues of soil organisms, and substances synthesized by the soil population.

(10) "Soil pH" is the negative logarithm to the base 10 of the hydrogen ion activity of a soil as determined by means of a suitable sensing electrode coupled with a suitable reference electrode at a 1 : 1 soil : water ratio.

(11) "Soil series" is the basic unit of soil classification. It is a subdivision of a family, and it consists of soils which are essentially alike in all major profile characteristics except the texture of the "A" horizon.

(12) "Soil texture" refers to the classification of soils based on the relative proportions of the various soil separates present (i.e., clay, sandy clay, silty clay, clay loam, silty clay loam, sandy clay loam, loam, silt loam, silt, sandy loam, loamy sand, sand).

(c) *Good laboratory practice.* The Good Laboratory Practice Standards for Physical, Chemical, Persistence, and Ecological Effects Testing, in § 772.110–2, must be followed in performing this standard.

(d) *Conditions.* (1) The number and type of soils to be used will be specified in the Test Rule.

(2) Equipment required: Distilled-deionized water adjusted to pH 7 by boiling to remove CO_2; clean glass plates (TLC); glass rods or a variable thickness plate spreader; masking tape; closed chromatographic chambers; analytical instrumentation necessary and appropriate for the detection and quantitative analysis of the test chemical.

(3) The test procedure may be run at 23 ± 5°C.

(4) Only gentle crushing and grinding of the air dried soil must be employed to reduce aggregate size before or during sieving.

(e) *Procedures.* (1) First, air dried soils must be sieved at 250 micrometers.

(2) Water must be added to the sieved soil until a smooth, moderately fluid slurry is attained (approximately ¾ ml H_2O added for each gram of soil).

(3) The soil slurry must be evenly and quickly spread across the clean glass plate by use of a variable thickness plate spreader, use of a glass rod, or other available methods. If a glass rod is used, layer thickness must be controlled by affixing multiple layers of masking tape along the plate edges. Soil layer thickness must be 500–750 micrometers.

(4) The plates must be air dried at 25°C for a minimum of 24 hours after uniform slurry application is achieved.

(5) A horizontal line must be scribed 11.5 cm above the base through the soil layer down to the glass so as to stop solvent movement.

(6) The test chemical must then be spotted at 1.5 cm above the base. For radiolabeled materials 0.5–5 μg

containing 0.01–0.03 μCi of 14_C labeled compound may be used.

(7) At least three replicate plates must be used for each soil.

(8) If the compound is volatile, a clean plate must be placed over the soil TLC plate to impede volatilization.

(9) The plate must be immersed base down at some angle from the vertical in a closed chromatographic chamber containing H_2O at a height of 0.5 cm.

(10) The solvent front must migrate to the 11.5 cm line before the plates are removed from the chamber.

(11) R_f values must be determined. Zonal extraction, plate scanning, or any other method or combination of methods suitable for detection of the parent test chemical may be used.

(12) A mass balance for the parent test chemical must be performed by determining the amount of the parent test chemical on the entire soil TLC plate after test chemical migration. Any method or combination of methods suitable for the extraction and quantitative detection of the parent test chemical may be used.

(f) *Reporting.* Information specified in § 772.110–2(h) of the Good Laboratory Practice Standards must be reported. Also, the following information must be reported using the following Figures 1 and 2:

FIGURE 1 - SOIL TLC DATA FORMAT

SOIL:

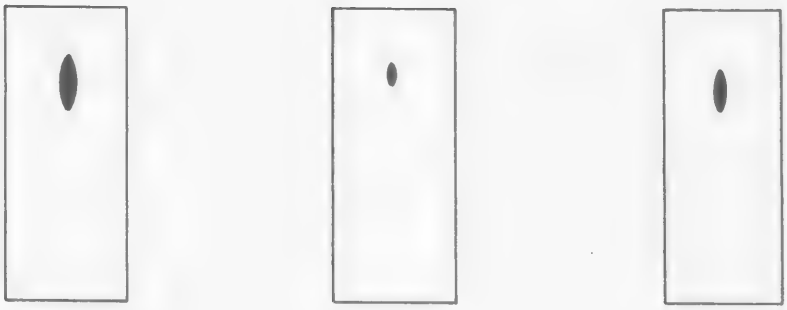


PLATE 1 PLATE 2 PLATE 3

QUANTITY	PLATE 1	PLATE 2	PLATE 3
R_f			
Amount Applied			
Amount Recovered			
% Recovered			
Mean R_f			
Standard Deviation			

Figure 2.—*Soil physical, chemical, and classification data format*

	Soil 1	Soil 2
Soil order	Alfisol	
Soil series	Crider	
Soil texture	Silt loam	
Location	Gallatin County, IL	
Horizon	B	
Percent sand	1.2	
Percent silt	86.6	
Percent clay	12.2	
Percent organic matter	1.74	
pH (1:1 H_2O)	7.20	
CEC (MEQ/100GMS)	13.5	
Clay fraction mineralogy	75 percent montmorillonite; 5 to 20 percent, mica; 5 percent, kaolinite (36 to 120 cm depth).	

(1) temperature at which the test was conducted, (2) amount of the test chemical applied and amount recovered from the plates, (3) detailed description of the analytical technique used in the R_f determination, the chemical extraction, and the quantitative recovery and analysis of the parent chemical; (4) the mean frontal R_f value with the standard deviation for each soil tested; (5) a photograph or diagram of the TLC plate which shows the entire leaching pattern (from 1.5 to 11.5 cm); (6) soil information: soil order, series, texture, sampling location, horizon, general clay fraction mineralogy; and (7) soil physical-chemical properties: percent sand, percent silt and percent clay (particle size analysis); percent organic matter; pH (1:1 H_2O); and cation exchange capacity.

[FR Doc. 80–36045 Filed 11–20–80; 8:45 am]

BILLING CODE 4510–31–M

40 CFR Part 772

[OPTS–46004A; TSH FRL 1594–4]

Physical, Chemical, Persistence, and Ecological Effects Testing; Proposed Good Laboratory Practice Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This notice proposes good laboratory practice (GLP) standards for the development of data on physical, chemical, persistence, and ecological effects fo chemical substances for which EPA will require testing under section 4 of the Toxic Substances Control Act (TSCA) (Pub. L. 94–469, 90 Stat. 2003, 15 U.S.C., 2601, et seq.). These proposed standards supplement "Good Laboratory Practice Standards and Health Effects," proposed on May 9, 1979 (44 FR 27362). The good laboratory practice standards include general standards that apply to all laboratory testing for physical, chemical,

persistence, and ecological effects under section 4 of TSCA. When these proposed good laboratory practice standards are made final, they will be included as requirements, where appropriate, in testing rules promulgated for specific chemicals. Compliance with these standards will assure the reliability and adequacy of data submitted pursuant to testing rules promulgatged under section 4.

DATES: Written comments should be submitted on or before January 21, 1981. Oral comment will be received on February 10, 1981. See Supplementary Information for public meeting information.

ADDRESS: Written views and comments should bear the EPA document control number OPTS–46004A and should be submitted to: Document Control Officer, (TS–793), Management Support Division, Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E–447, 401 M St., SW., Washington, D.C. 20460, (202–755–8050).

FOR FURTHER INFORMATION CONTACT: John B. Ritch, Jr., Industry Assistance Office, (TS–799), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E–427, 401 M St., SW., Washington, D.C. 20460, (800–424–9065), In Washington, D.C.: (554–1404).

SUPPLEMENTARY INFORMATION:

I. Introduction

Under section 4(b) of TSCA (90 Stat. 2003, et seq., 15 U.S.C., 2601 et seq.), EPA is preparing proposals for standards for the development of test data. These data are to be used to determine if particular chemicals present, or do not present, unreasonable risks to health or the environment. The proposal consists of this notice, a separate notice titled, "Proposed environmental effects test standards for Toxic Substances Act test rules—Physical, chemical, and environmental persistence characteristics," which appears elsewhere in this copy of the **Federal Register**, and previously proposed test standards published in the **Federal Register** of May 9, 1979 (44 FR 27334), and July 26, 1979 (44 FR 44054).

In this notice, EPA is proposing general Good Laboratory Practice (GLP) Standards for Physical, Chemical, Persistence, and Ecological Effects Testing. These GLP Standards are designed to assure the reliability and adequacy of data submitted, and are issued to supplement previously proposed GLP Standards for Health Effects (44 FR 27362) issued on May 9, 1979. These practices are proposed to apply generally to all testing for physical, chemical, persistence, and ecological effects conducted under section 4 of TSCA, by or on behalf of manufacturers or processors of chemical substances or mixtures.

Separate GLP standards for health effects testing and physical, chemical, persistence, and ecological effects testing are necessary for a number of reasons. Testing to be conducted in accordance with proposed health effects standards is primarily concerned with effects on a limited number of animal species. It does not address the analytical problems associated with physical, chemical, and persistence testing nor does it address the special problems associated with the wide variety of vertebrates, invertebrates, and plant species covered in ecological effects testing.

While these GLP Standards will apply generally to all prescribed tests for physical, chemical, persistence, and ecological effects, individual tests may contain specific GLP instructions that apply to that particular test.

II. Previously Proposed Good Laboratory Practice Standards for Health Effects

EPA proposed new Parts 770, 771, and 772 to be added to Chapter I of Title 40 of the Code of Federal Regulations, published in the **Federal Register** of May 9, 1979 (44 FR 27335). The preamble to proposed test standards for physical, chemical, and environmental persistence characteristics, which appear elsewhere in this issue of the **Federal Register**, outlines the content of the several parts and subparts.

Part of the proposal of May 9, 1979, included proposed Good Laboratory Practice Standards for Health Effects (frequently cited simply as "Health GLP") (44 FR 27362) for inclusion in 40 CFR 772.110–1. Proposed GLP Standards for Physical, Chemical, and Environmental Persistence Characteristics and Ecological Effects Testing presented here are for inclusion as § 772.110–2, in the same part and subpart identified for the Health GLP.

Preamble discussions of the authority and need for GLP Standards as they apply to testing for health effects are, in general, equally applicable to these proposed standards. Problems with the adequacy of testing data were identified by the Food and Drug Administration (FDA) in the mid 1970's and were reported to the Senate Subcommittee on Health (Committee on Labor and Public Welfare). FDA's inspections of several pharmaceutical houses and contract laboratories found unacceptable laboratory practices that, in turn, called into question the validity of test data submitted. Unacceptable practices included selective reporting and underreporting of results, lack of adherence to specified protocols, inadequate qualification and supervision of personnel, poor animal care procedures, poor recordkeeping techniques, and the general failure of sponsors to monitor studies. Later inspections and audits done jointly by FDA and EPA also indicated that testing facilities do not always follow good laboratory practices.

III. Proposed Good Laboratory Practice Standards

These proposed GLP Standards prescribe methodology for the selection, handling, and storage of the test substance; personnel qualifications, and the organization of the testing laboratory; minimal facilities; equipment specifications; operation of the testing facilities; requirements for a study plan and the conduct of a study; requirements for recordkeeping and reports; and specific appendices applicable to testing for physical, chemical, and persistence characteristics and to testing for ecological effects. Proposed GLP Standards for Physical, Chemical, and Persistence Characteristics and Ecological Effects Testing have been harmonized as much as possible with the proposed GLP Standards for Health Effects Testing. The Health GLP Standards have, in turn, been harmonized to the extent practicable with the GLP issued by the FDA. A detailed comparison is included in the preamble to the GLP Standards for Health Effects Testing.

Additional general discussion and comparisons with the Health GLP are presented in the following paragraphs and concentrate on differences between the Health and Environmental GLP Standards.

(a) *Introduction.* Statements of the authority, purpose, and scope of GLP Standards proposed here are similar to the authority and purpose stated for GLP Standards for Health. These GLP Standards for Physical, Chemical, and Persistence, and Ecological Effects Testing are consistent with the guidance for GLP issued by several professional societies and EPA program offices.

Definitions incorporated in these GLP Standards include several terms not included in the GLP Standards for Health, mainly because environmental testing covers different types of testing. Also, a few of the definitions are made broader, such as "testing facility," which will cover laboratories which perform a wider variety of testing, with different methods and test species, than do laboratories that do health testing.

(b) *Testing and control substances.* Requirements for documenting the purity of the test substance and for minimizing contamination or alteration during storage and handling are intended to assure consistency of testing results. The language of these proposed Standards differ slightly from the language in the Health GLP, but essentially the requirements on the testing laboratory are the same.

(c) *Organization and personnel.* This section of the standard is to assure that laboratories doing testing are staffed by personnel who are competent to do the testing, that the staff and laboratory are organized in a manner that is likely to lead to proper conduct of the tests, and that the laboratory has a suitable organization, staff, and procedures to implement good quality assurance. There are several small differences between requirements in this section and requirements in the Health GLP Standards. These GLP Standards, for example, require that the quality assurance unit monitor all work but it only recommends, not requires, that the unit be separate and independent from those conducting the work. This was made a recommendation in order to allow small laboratories with limited staffs some flexibility in conforming with this provision of the GLP Standards. These GLP Standards also require development of a quality assurance plan prior to starting of testing, not as testing proceeds, in order to make the plan available for Agency review at any time. These Standards also require maintaining a master schedule of all testing in order to provide an indication of total work load and allow evaluation of whether testing was done under overloaded conditions.

(d) *Facilities.* Requirements for facilities in this GLP Standard are considerably shorter than the requirements in the GLP Standards for Health because the Health GLP includes detailed standards for facilities for animals. This would be impractical to include in these Standards since such a wide variety of species are included in ecological effects testing standards. Therefore, specific requirements for facilities for testing for environmental effects using animals are proposed in § 772.110–4 of these proposed GLP Standards and in specific GLP sections of some individual test standards.

(e) *Equipment.* Standards are proposd in this section to assure that equipment in testing laboratories is properly designed and adequately maintained so that reliable data can be collected. In addition, the standards require that records be maintained of equipment inspection, maintenance, testing, calibration, standardization, failure, malfunction, and repair.

(f) *Testing facilities operation.* To assure consistent, high-quality data, testing laboratories are to have written standard operating procedures and adequate manuals and records also are to be maintained. The language of standards proposed in this section differs slightly from language in the health GLP in order to allow for different types of facilities needed for physical, chemical, persistence, and ecological testing. In addition to the GLP requirements for facilities in § 772.110–2(f), there also are requirements for special facilities for ecological effects testing outlined in § 772.110–4 of these proposed GLP Standards. Additional requirements for facilities also many be outlined in standards for individual tests because they are test specific.

(g) *Study plan and conduct of a study.* This section of the GLP Standard is to assure that tests of chemical substances are planned carefully, and then are carried out in accordance with the plan, or otherwise that deviations are documented. The wording of this section differs only slightly from that in the corresponding section of the Health GLP in order to allow for differences in the types of tests to which they apply. In addition, this GLP requires information on chemical stability which EPA regards as important in planning long-term tests or other types of test in which transformation of the chemical may affect results.

(h) *Records and reports.* Final reports from the testing of chemicals must be complete in order to permit EPA and the test sponsor to judge adequacy and reliability of data to be used in assessing the potential fate of or environmental hazard from a substance. Differences from the Health GLP are minor; one difference is that this Environmental GLP requires reporting of quality-assurance methods used in testing–a factor which EPA counts as important in judging acceptability of testing.

(i) *Physical, chemical, and persistence testing.* Testing for physical, chemical, and persistence characteristics has several specific GLP requirements above and beyond the requirements proposed in the main portion of these GLP Standards. These special requirements are detailed in § 772.110–3, and deal with special qualifications and training for personnel, and with special requirements for the testing laboratory. Persons who perform tests for physical, chemical, and persistence characteristics of chemicals need to have training and/or experience in chemistry, biology, microbiology, or closely related areas. Laboratories must have adequate space for a variety of specialized equipment. Special requirements are proposed to protect laboratory personnel from potentially dangerous exposure to sewage during certain microbiological tests.

(j) *Ecological effects testing.* Testing for ecological effects of chemical substances generally involves the exposure of a wide variety of plants and animals of chemical substances and mixtures. Consequently, there are many special GLP requirements that apply to the personnel, facilities, operation, planning and conduct, and reporting of ecological effects testing. These special GLP requirements are detailed in § 772.110–4 of this GLP Standard.

(1) *Personnel.* Several diseases and infections that affect people also may present a threat to the organisms involved in testing for ecological effects of chemical substances. Consequently, all illnesses of laboratory personnel are to be reported and infected persons who may affect the testing are to be excluded from contacting the test organisms.

Most testing of chemicals using fish, birds, other animals, or plants requires first the availability of organisms, and then their maintenance in often delicate cultures. It also may involve sophisticated analytical chemistry techniques as well as pathological examination. EPA, therefore, in these GLP Standards requires that the tests be conducted by personnel with sufficient training and/or experience in appropriate specialty areas such as biology, veterinary science, pathology, analytical chemistry, fisheries biology, and other specialty areas. In addition to the special requirements contained in § 772.110–4, some of the test standards for ecological testing also contain additional personnel requirements.

(2) *Facilities.* Testing of chemicals for ecological effects is likely to involve work with a large number of different types of plants and animals. Laboratories doing the testing must, therefore, have adequate facilities to care for the different test species, to avoid mixup, and to provide that the several different types of tests do not interfere with each other. Proposed GLP Standards in § 772.110–4, applicable to ecological effects testing, are intended to guard against such types of problems. Reference is made to general provisions to the Animal Welfare Act and to other general standards for the care and testing of animals (including fish). The standards require adequate rooms for separation of species and tests where interferences may result, but they do not require categorical separation of all

species or of all different types of tests. Separate spaces are required for certain aseptic procedures, for cleaning and maintenance of equipment, and for facilities for personnel such as lockers, showers, toilets, and washing areas.

(3) *Testing facilities operation.* Section 772.110–4 outlines the requirements for standard operating procedures for the handling of organisms, and includes specific paragraphs on special aspects of care for and handling of organisms. These special GLP provisions are intended to assure that testing is done with strong, healthy organisms, and that the test results are not affected by mix-up or by damage from poor handling or extraneous factors

(4) *Study plan and conduct of a study.* In addition to general requirements for a study plan and conduct of testing outlined in § 772.110–2(g) of these GLP Standards, § 772.110–4(e) provides for specific requirements for testing for ecological effects. The study plan needs to consider how test organisms are selected, as well as their indentification, feeding, and methods of dosing with the test chemical. This § 772.110–4(e) also requires specific indentification of test organisms and identification of gross findings by a pathologist doing a histopathological examination.

(5) *Reporting of the study results.* Reports of ecological effects testing are to include specific details on the numbers and types of test organisms, and on the chemical dosages adminsitered and the manner in which they were administered.

(k) *Inspection of testing facility.* The Agency will conduct inspections of testing facilities and audits of data developed by those facilities if the testing was, or is being done in support of TSCA regulations according to Part 772, Subparts L, M, or N.

IV. Economic Analysis

These GLP standards are very similar to FDA's Good Laboratory Practice Regulations for Nonclinical Laboratory Studies which became law on June 20, 1979. By now, after several years of industry-wide discussion and development of the FDA GLP's and after one year of actual enforcement, regulations have already impacted the cost of performing animal toxicity studies. Thus, it is conceivable that the proposed EPA GLP environmental standards will have little or no further impact on testing costs in laboratories which conduct both health effects and environmental effects testing. In addition, many of the laboratories that do environmental testing already adhere to similar GLP requirements issued by EPA program offices and several professional societies such as the American Public Health Association (APHA), American Water Works Association (AWWA), the American Society for Testing and Materials (ASTM), and the EPA program offices for water and pesticides.

Due to the fact that Good Laboratory Practice standards are not specific protocols, it is impossible to provide an itemized component cost breakdown. In fact, GLP's represent operational procedures which are designed to affect all methods and tests. Thus, the economic impact of GLP standards can only be measured in terms of their relative impact, e.g., percentage increase, upon the cost of performing any and all tests.

Private estimates from industrial and independent contract testing laboratories secured by EPA contractors have ranged from 10 to 80 percent increase in the cost of testing; the general consensus being that GOP regulations have increased testing costs by an average of 50 percent over pre-GLP prices. Unfortunately, it is impossible at this time to obtain a more accurate estimate of the economic impact of GLP regulations

The following examples demonstrate how GLP standards are actually operational procedures and why it is impossible to calculate an itemized component cost breakdown:

(1) Most laboratories did not have a Quality Assurance Unit (QAU) in early pre-GLP times. Much of the time spent by QAU personnel can be charged as a Direct Labor Cost on a study, but quite often the QA Unit is partially supported by overhead. The impact of this overhead expense depends on the size of the unit, the salaries paid, the size of the laboratory, the relative magnitude of the overhead burden, and the efficiency with which the QAU performs its job.

(2) The preparation of Standard Operating Procedures (SOP) is entirely an overhead expense. It takes management, technical (both senior and junior), and clerical time to write SOP's initially and to continually update them. The use of SOP's does probably increase technical efficiency and minimize training time. The magnitude of these effects depends upon whether or not a laboratory previously had SOP'S.

(3) Other procedures regarding test articles, protocols, record keeping, etc. undoubtedly add additional labor costs to each test. The magnitude of the impact depends upon procedures which were followed before GLP's came into effect.

(4) Other requirements concerning the adequacy and design of facilities; the adequacy, maintenance, and calibration of equipment; and the adequacy, supervision, training, and experience of available technical and management personnel are impossible to describe in terms of economic impact on test costs due to variations in the availability of these resources at each laboratory, both before and after GLP's became law.

EPA will do an economic analysis to estimate the cost of testing for each environmental test standard proposed in Subparts L and M. Each estimate will be made on the assumption that these GLP standards apply, and therefore will include GLP incremental costs in the total cost estimated for each test.

V. Public Record

EPA has established a public record for this rulemaking (document number OPTS–46004A) which along with a complete index is available for inspection in the OPTS Reading Room from 8:00 a.m. to 4:00 p.m. (Rm E–447, 401 M St., SW., Washington, D.C. 20460). This record includes basic information considered by the Agency in developing this proposal. The Agency will supplement the record with additional information as it is received. The record includes the following information:

(1) USEPA–OPTS. "Proposed Physical, Chemical, Persistence and Ecological Effects Test Standards for Toxic Substance Control Act Test Rules."

(2) USEPA–OPTS. "Proposed Physical, Chemical, Persistence and Ecological Effects Test Standards for Toxic Substance Control Act Test Rules Support Document."

(3) USEPA–OPTS. "Toxic Substances Control Act Premanufacture Testing of New Chemical Substances" (44 FR 16240) and all public comments received on this discussion document.

(4) USEPA–OPTS. "Proposed Good Laboratory Practice Standards for Health Effects" (44 FR 27369 et seq.).

(5) USEPA–OPP. "Proposed Guidelines for Registering Pesticides in the United States" (43 FR 29696–740).

(6) USEPA–OPP. "Guidelines for Registering Pesticides in the United States" (40 FR 26802–928).

(7) Drafts of the proposed rules, the preamble, and the support document which were available for public comment.

(8) Correspondence pertaining to the development of the standards, the preamble, or the support document. (This does not include inter- or intra-agency correspondence, unless specifically noted in the index to the rulemaking record).

(9) Minutes, summaries, or transcripts relating to public meetings held to develop the standards.

(10) Scientific papers relevant to issues relating to these tests which were used by the agency in developing this proposal.

(11) Contractor's report, "Cost Analysis Methodology and Protocol Estimates: Environmental Standards," by Enviro Control, Inc., April 28, 1980, 26 p.

Published documents cited in this preamble are incorporated in the record by reference. EPA will accept additional and relevant material for the record at any time between this proposal and the final designation of the rulemaking record, on or before the date of promulgation of these requirements as prescribed by TSCA section 19(a)(3).

VI. Public Meetings

EPA personnel responsible for developing these proposed Environmental Test Standards will be available to meet with interested persons from companies, trade associations, organized labor and citizen organizations on February 10, 1981 at: Skyline Inn, South Capitol & I Streets, SW., Washington, D.C.

The meeting will be from 1 p.m. to 5 p.m. This location is three blocks east of the EPA Headquarters, Waterside Mall, 401 M St., SW., Washington, D.C. Persons who wish to make presentations should request time by contacting the Industry Assistance Office by telephone, either toll free (800–424–9065) or on 554–1404 in Washington. Time will be scheduled between 1 p.m. and 5 p.m. The Agency will make a transcript of the sessions for inclusion in the official public record. Participation in a session will be limited to those who have requested that time to make oral comment.

One purpose of providing this opportunity for oral comment is to provide EPA with information on costs and approaches to compliance for impacted companies, especially small ones. The other purpose of this public meeting is to allow EPA to digest the scope and nature of written comments on scientific and technical points before hearing oral argument or comment on them. The Agency's general criterion for allotting time will be that a person has an interpretation, data or experience that is best presented orally with the opportunity for cross-checking communication with the Agency. In this case, an additional criterion will be that a person has a review of the written commentary already submitted to share with the Agency. EPA's experience has shown that this roundtable format for public meetings by request that are open to the public yields more productive exchanges for both commentators and the Agency. EPA encourages commentators to use the toll free telephone to ask questions of clarification early in the written comment period to aid their formulating their comments.

Note.—Under Executive Order 12044, EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized." This regulation has been reviewed and it has been determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

(Sec. 4, TSCA, 90 Stat. 2006; 15 U.S.C. 2603)

Dated: September 25, 1980.

Douglas M. Costle,

Administrator.

Therefore, EPA proposes to add new §§ 772.110–2, 772.110–3, and 772.110–4 to Subpart B of Part 772 to read as follows:

§ 772.110–2 Good laboratory practice standards for physical, chemical, persistence, and ecological effects testing.

(a) *Introduction*—(1) *Scope and purpose.* The requirements contained in these standards apply to all testing for chemical, physical, and environmental persistence characteristics, and for ecological effects. Compliance with the standards is intended to assure the quality and integrity of data filed pursuant to section 4 of the Toxic Substances Control Act (TSCA) (Pub. L. 94–469, 90 Stat. 2003, 15 U.S.C. 2601 et seq.). When interpreting specific requirements, the differences between laboratories conducting physical, chemical, and persistence tests and those conducting biological tests should be recognized. Section 772.110–3 of these standards contains special material applicable to physical, chemical, and persistence testing, and § 772.110–4 has material applicable to ecological testing.

(2) *Applicability*—(i) *General.* Requirements set forth in these standards apply to the development of all data on chemical, physical, and environmental persistence characteristics, and on ecological effects submitted to the Environmental Protection Agency (EPA) by chemical manufacturers and processors in compliance with section 4 test rules promulgated under TSCA. Where more specific or detailed GLP requirements are required by the EPA, these exceptions will be incorporated into the specific test standards or test rules.

(ii) *Applicability to studies performed under grants and contracts.* When a sponsor conducting a study intended to be submitted to or reviewed by the EPA uses the services of a consulting laboratory, contractor, or grantee to perform an analysis or other service, the sponsor must notify the consulting laboratory, contractor or grantee that the service is part of a study that must be conducted in compliance with the provisions of these standards.

(3) *Definitions.* (i) "Batch" means a specific quantity or lot of a test or control substance.

(ii) "Biohazardous" means toxic to organisms or biological systems.

(iii) "Chemical fate testing" means activities relating to or performed for the characterization of physical, chemical, and persistence factors that determine the fate of test substances and their transformation products in soil, water, and air.

(iv) "Control substance" means any chemical substance or mixture administered to the test system in the course of a study for establishing a basis for comparison with the test substance.

(v) "Ecological effects testing" means activities relating to or performed for the generation of information on non-human toxicity and potential ecological impact of test substances and their degradation products.

(vi) "Impurity" means any ingredient present in a batch or preparation, other than a specified active ingredient or intentionally added inert ingredient, and includes impurities, contaminants, reaction products, and degradation products.

(vii) "Intentionally added inert ingredient" means any inert ingredient which is intentionally added to the technical active ingredient, or to the manufacturing-use product.

(viii) "Pathobiology" includes the study of abnormal tissue formed as a result of treatment of organisms with, or exposure to, toxic substances.

(ix) "Person" means an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

(x) "Quality assurance unit" means any person or organizational element of the testing facility, except the study director, designated by the testing facility management to perform the duties relating to the quality assurance unit specified herein.

(xi) "Raw data" means all data recorded in laboratory worksheets, notebooks, records, memoranda, notes, or recording devices, or exact copies thereof resulting from original observations and activities of a study and necessary for the reconstruction and evaluation of the report of the study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed

verbatim, dated, and verified accurate by signature of the originator), the exact copy or exact transcript may substitute for the original source as raw data. "Raw data" may include photographs, microfilm or microfiche copies, computer printouts, magnetic media including dictated observations, recorded data from automated instruments, and correspondence relating to the planning, conduct, and interpretation of the study.

(xii) "Specimen" means any material derived from a test system for examination or analysis.

(xiii) "Sponsor" means a person who is required by a test rule under section 4 of TSCA to submit to the EPA data developed pursuant to such test rule. The test sponsor is the manufacturer, processor, or person who intends to manufacture or process chemical substances and mixtures subject to said rule and who conducts, commissions, or otherwise develops or has developed the data required by said rule.

(xiv) "Study" means a careful analysis or examination of knowledge used to measure a parameter or parameters.

(xv) "Study director" means the individual responsible for the overall conduct of a study.

(xvi) "Testing facility" means a person as defined above who actually conducts a study, i.e., actually uses the test substance or mixture in a test system. "Testing facility" encompasses any establishment that conducts laboratory studies required under TSCA. It includes:

(A) The buildings, laboratories, laboratory equipment, animal quarters, aquatic holding areas, greenhouses, insectory, growth chambers, testing units (including artificial and natural streams and ponds, fields, or enclosures), storerooms, refrigeration room, preparation rooms, and other premises in which experimental studies and activities pertaining to experimental studies are conducted.

(B) The corporate or other legal entity which owns, operates, or otherwise controls the physical premises and research operations described in paragraph (a)(1)(xvi)(A) of this section.

(C) The owners, managers, scientists, technicians, animal caretakers, and other persons who plan and conduct experiments, analyze data, and otherwise develop the data required by said rule.

(xvii) "Test standard" means a method promulgated or approved by the Agency to measure certain chemical fate and ecological effects parameters under TSCA.

(xviii) "Test substance" means the specific chemical substance or mixture that is used to develop data to meet the requirements of a TSCA section 4 test rule.

(xix) "Test system" means any apparatus, environment, ecosystem, animal, plant, microorganism, or subparts thereof to which the test or control substance is administered or added for study. "Test system" also includes appropriate groups or components of the system not treated with the test or control substances or mixtures.

(4) *Quality control.* Quality control procedures which form the basis for quality assurance are found in study plans, as described under paragraph (g)(1) of this section. Quality control procedures include instrument calibration and standardization, purity checks on reagents and reference standards, statistical design, and other actions to maintain the standards of the test being performed. Quality assurance procedures provide oversight to test performance in general.

(b) *Test and control substances*—(1) *Characterization.* (i) The identity, purity, and composition or other characteristics which appropriately define the test or control substances must be determined for each batch to be studied and documented before the study begins. Impurities must be defined to the extent required by regulations promulgated under TSCA.

(ii) The batch of the substance tested must be as specified in test rules promulgated by EPA and, unless otherwise specified, must be the same throughout the entire study. If the same batch is required but cannot be used throughout the study because of chemical instability or other relevant factors, other batches of the test substance as nearly identical to the original batch as feasible must be used. Appropriate qualitative and quantitative chemical tests must be performed to verify this identity, and any deviation in identity must be documented and reported.

(iii) If the source characteristics of the test and control substances may impact on the test results, they must be documented by the sponsor or the testing facility by identifying information such as method of derivation, synthesis, fabrication, and purification.

(iv) Since proper evaluation of test results is dependent upon the integrity of the material being tested, the stability of each test or control substance must be ascertained under the conditions of storage and use or application as relevant to any study or part thereof by the testing facility or by the sponsor before initiation of the study. When the test or control substance has deteriorated beyond a limit specified in the study plan, the substance must not be used for tests.

(v) Each storage container for a test or control substance must be labeled by name of the substance, chemical abstract number (CAS) or code number, batch number, expiration date and, where appropriate, storage conditions necessary to maintain the identity, purity, and composition of the test or control substance. Storage containers must be assigned to one particular test substance only for the duration of the study. No container may be used which will contaminate the test or control substance in such a way as to invalidate test results.

(vi) When samples of test and control substances are required to be retained, those samples must be retained for the period of time provided by paragraph (h)(3)(ii) of this section and must be stored and maintained as specified in paragraph (h) (2) and (3) (iii) of this section.

(2) *Handling.* (i) Procedures must be established for the handling of test and control substances to ensure that:

(A) There is proper storage in an area with restricted access under conditions that will ensure stability and integrity of the test and control substances.

(B) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.

(C) The substances are properly identified throughout the distribution process.

(D) The receipt and distribution of each batch is documented. Such documentation must include the date and quantity of each batch distributed or returned.

(ii) To assure that any potentially adverse effect on testing facility personnel due to toxic substances being evaluated be minimized, appropriate recommendations of the Department of Health and Human Services on the handling of carcinogens should be followed. For other toxic, but noncarcinogenic substances, methods for safe handling and disposal in general use, e.g., as described in appropriate section 29 CFR Part 1910, OSHA Standards or applicable regulations in other countries, and published manuals for laboratory safety, should apply.

(iii) If radioactive materials are used, special facilities or areas and licensing of persons to possess and use radioactive materials should be in accordance with regulations set forth by the Nuclear Regulatory Commission.

(iv) Substances that may react violently, explode, or spontaneously burn must be handled and protected in

such a way that possible undesirable events will not occur.

(3) *Mixtures of substances with carriers.* (i) For each test or control substance that is mixed with or dissolved in a carrier, tests by appropriate analytical methods must be conducted to:

(A) Determine the uniformity of the mixture and, periodically, the concentration of the test or control substance in the mixture. When the mixture has deteriorated beyond a limit specified in the study plan, the mixture may not be used for tests.

(B) Determine the stability of the test and control substance when they are part of the mixture.

(ii) A record must be kept of the preparation and usage of each treatment mixture, including the dates, quantities prepared or used and the names of the responsible individuals.

(iii) When samples of test-carrier or control-carrier mixtures are required to be retained those samples must be taken and retained for the period of time provided by paragraph (h)(3)(ii) of this section.

(iv) Where any of the components of the test-carrier or control-carrier mixture has an expiration date, that date must be clearly shown on the container. If more than one component has an expiration date, the earliest date must be shown.

(c) *Organization and personnel*—(1) *Personnel.* (1) Each individual engaged in the conduct of or responsible for the supervision of a study must have adequate education, training, and/or experience to perform the assigned functions. Each individual supervising tests must have an educational level equal to or exceeding a professional degree, or equivalent experience, in the relevant subject matter.

(ii) Each testing facility must maintain a current summary of training and experience and a job description for each individual engaged in or supervising the conduct of a study. The Environmental Protection Agency may, at any time, request such summaries from the test sponsor.

(iii) There must be sufficient personnel available for the timely and proper conduct of the study according to the study plan.

(iv) Personnel must take necessary personal sanitation and health precautions to avoid contamination of test and control substances and test systems and to minimize exposure of personnel to toxic substances.

(v) Personnel engaged in a study must wear clothing appropriate for the duties they perform. Such clothing must be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test and control substances and to minimize exposure of personnel to such materials.

(2) *Testing facility management.* For each study, the testing facility management must:

(i) Designate a study director as described in paragraph (c)(3) of this section before the study is initiated.

(ii) Replace the study director promptly if it becomes necessary to do so during the conduct of a study, and document and maintain such action as raw data.

(iii) Assure that there is a quality assurance unit as described in paragrpah (c)(4) of this section.

(iv) Assure that personnel, resources, facilities, equipment, materiel and study plans required for the study are available as scheduled.

(v) Assure that personnel are qualified for and clearly understand the functions they will perform.

(vi) Assure any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.

(vii) Assure that the test facility operation conforms with OSHA standards and guidelines for health and safety of the personnel.

(3) *Study Director.* For each study, a scientist or other professional of appropriate education, training, and experience must be identified as the study director. The study director is responsible for the overall conduct and reporting of the study and for implementation of the approved study plan. The study director must assure that:

(i) The study plan, including any change, is approved as provided by paragraph (g)(1)(i) of this section and followed.

(ii) Test and control substances or mixtures have been appropriately tested for identity, purity, composition, stability, and uniformity as applicable.

(iii) All experimental data, including observations of unanticipated responses to the test system, are accurately recorded and verified.

(iv) Unforeseen circumstances that may require deviation from approved methods and study plans and may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented. The study director is responsible for proper documentation of such events and for the evaluation of their effects on the overall study objectives.

(v) Test systems are as specified in the study plan.

(vi) All applicable good laboratory practice standards are followed.

(vii) All raw data, documents, study plans, specimens, and final reports are transferred to the archives during, or at the close of, the study.

(4) *Quality assurance unit.* (i) A testing facility must have a quality assurance unit composed of one or more individuals responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls conform to these standards. Each facility's quality assurance unit must also monitor each study performed by contractors or grantees. It is recommended that the quality assurance functions be separate and independent of personnel engaged in the direction and conduct of a study. In all cases, a quality assurance plan must be prepared by the testing organization prior to initiation of the study and be available for Agency review upon request.

(ii) The quality assurance unit must:

(A) Maintain and make available for examination a copy of a master schedule sheet of all TSCA-related studies conducted at the testing facility, indexed by test substance and describing the test system, nature of the study, date the study was initiated, current status of each study, name of the sponsor, name of the study director, and status of the final report.

(B) Maintain copies of all study plans pertaining to all TSCA-related studies for which the unit is responsible.

(C) Review and approve the quality assurance section of each study plan.

(D) Periodically inspect each phase of each type of study performed or, in the case of routine chemical or physical determinations, the conduct of each kind of analysis, and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for reinspection. Inspections must be conducted at least every three months to assure the integrity of the study. Any significant problems found during the course of an inspection and likely to affect study integrity must be brought to the attention of the study director and management immediately.

(E) Submit to management and the study director periodic written status reports on each study, noting any problems and the corrective actions taken.

(F) Ascertain that all deviations from sponsor-approved study plans or

standard operating procedures and the pertaining authorizations are properly documented.

(G) Review the final study report to assure that such report accurately describes the methods and standard operating procedures and that the reported results accurately reflect the raw data of the study.

(H) Prepare and sign a statement, to be included with the final study report, which specifies the dates inspections were made and findings reported to management and to the study director.

(iii) Written notices of the responsibilities and procedures applicable to the quality assurance unit, a list of the records maintained by the quality assurance unit, and the method of indexing such records must be maintained. These items, including inspection dates, the study inspected, the phase or segment of the study inspected, and the name(s) of the individual(s) performing the inspection, must be made available to authorized employees of the EPA.

(iv) A designated representative of the EPA must have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented, and followed up in accordance with this paragraph.

(v) All records maintained by the quality assurance unit must be kept in one location at the testing facility.

(d) *Facilities*—(1) *General.* (i) Each testing facility must be of suitable size, construction and location to allow the proper conduct of studies. It must be designed to prevent any function or activity from adversely affecting the study.

(ii) The testing facility and test system, as defined in paragraph (a)(3) of this section, must conform to OSHA standards and guidelines for health and safety of personnel.

(iii) The facilities must have provisions to regulate temperature and humidity, as and when specified in the protocol.

(2) *Facilities for handling test and control substances.*

(i) As necessary to prevent contamination or mix-ups, the following areas must be physically separated from any area used for testing the test substances:

(A) Areas used for receipt and storage of the test and control substances.

(B) Areas used for mixing of the test and control substances with a carrier, e.g., feed or water, and preparation of stock solutions of the test substances.

(C) Areas used for storage of the test and control substance mixtures.

(ii) Storage areas for the test and control substances and for mixtures containing test and control substances must be separate from areas housing the test systems and be adequate to preserve the identity, concentration, purity, and stability of the substances and mixtures.

(3) *Specimen and data storage facilities.* Space must be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies, as detailed in paragraph (h)(2) and (3) of this section.

(4) *Administrative and personnel facilities.* Space must be provided for the administration, supervision, and direction of the testing facility.

(e) *Equipment*—(1) *Equipment design.* Automatic, mechanical, or electronic equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control must be of appropriate design and adequate sensitivity and capacity to function according to the study plan and must be suitably located for operation, inspection, cleaning, and maintenance.

(2) *Maintenance and calibration of equipment.* (i) The written standard operating procedures required under paragraph (f)(1) of this section must show in sufficient detail the methods, materials and schedules used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment. They must also specify remedial action to be taken if failure or malfunction of equipment occurs. The written standard operating procedures must designate the person responsible for the performance of each operation, and copies of the standard operating procedures must be made available to laboratory personnel.

(ii) Written records must be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records must contain the date of the operation and describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records must be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records must document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.

(f) *Testing facilities operation*—(1) *Standard operating procedures.* (i) A testing facility must have written standard operating procedures that describe study methods that satisfy management as being adequate to ensure the quality and integrity of the data generated during the study. The study director must authorize all deviations in a study from standard operating procedures and document them in the raw data.

(ii) Standard operating procedures must be established for, but not limited to, the following:

(A) Recipt, identification, storage, handling, mixing, and method of sampling of the test and control substances and mixtures.

(B) Description and method of operation of test system.

(C) Data handling, storage, and retrieval.

(D) Maintenance and calibration of equipment.

(E) Disposal of toxic and hazardous wastes in accordance with regulations.

(F) Quality control procedures used in tests and test system observations, data management, and organism maintenance.

(iii) Each laboratory area must have have immediately available laboratory procedures being performed, e.g., pertaining to toxicology, histology, physical chemistry, analytical chemistry, hematology, morphology, teratology, necropsy, or microbial culturing. Published literature may supplement standard operating procedures.

(iv) An historical file of standard operating procedures and all revisions thereof, including the dates of such revisions, must be maintained.

(2) *Reagents and solutions.* All reagents and solutions in the laboratory must be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions must not be used.

(g) *Study plan and conduct of a study*—(1) *Study plan.* (i) Each study must follow a written study plan approved by the sponsor that clearly indicates the objectives and all methods for the conduct of the study. The study plan must contain, but not be limited to, the following information:

(A) A descriptive title and statement of the purpose of the study.

(B) Identification of the test and control substance or mixture by name, chemical abstract (CAS) number, or referenced code number.

(C) Stability, shelf life, and expiration date, where applicable, of the test and control substance or mixture.

(D) The name of the sponsor and the name and address of the testing facility conducting the study.

(E) The proposed starting and completion dates.

(F) A description of the experimental design, including, where applicable, the test standard to be used, as promulgated or approved by the Agency, the methods for control of bias, statistical considerations concerning the experimental design, the number of blind, blank, spiked, split, and recycled samples, and precision and accuracy statements.

(G) Where applicable, the type and frequency of test, analyses, and measurements to be made.

(H) A statement of the proposed statistical methods to be used for the evaluation of the test results.

(I) The records to be maintained.

(J) The date of approval of the protocol by the sponsor and the signature of the study director.

(ii) The following information need not be included in the study plan but must be available for audit:

(A) A description of the testing equipment and instrumentation, where applicable, including maintenance and calibration procedures and frequencies.

(B) A quality assurance plan that described in detail all quality assurance aspects pertaining to the study. This quality assurance plan must be reviewed and approved by the quality assurance unit.

(C) The names and resumes of the study director and principal investigators, including a list by position and function of personnel planned to be allocated to the study.

(iii) All changes in or revisions of the sponsor-approved study plan and the reasons therefor must be documented, signed by the study director, dated and maintained with the study plan.

(iv) In addition to the study plan requirements as described in paragraph (g) (i), (ii) and (iii) of this section, additional requirements may be specified in appropriate test standards or test rules.

(2) *Conduct of a study.* (i) The study must be conducted in accordance with the study plan.

(ii) Each phase of the study must be supervised and conducted by trained and informed individuals.

(iii) The test system must be monitored in conformity with the study plan.

(iv) All data generated during the conduct of a study, except those that are generated as direct computer input, must be recorded directly, promptly, legibly, and indelibly. All data entries must be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries must be made so as to avoid obscuring the original entry, must indicate the reasons for such change and be dated and signed or identified at the time of the change. In computer-driven data collection systems, the individual reponsible for direct data input must be identified at the time of data input. Any change in computer entries must be recorded in a separate log which must include the original data entry, indicate the reason for change, be dated, and identify the individual responsible for making the change.

(h) *Records and reports*—(1) *Reporting of study results.* (i) A final report must be prepared for each study and include, but not be limited to, the following:

(A) Name and address of the facility performing the study and the dates on which the study was started and completed.

(B) Objectives and procedures stated in the approved study plan, including any changes in the original study plan.

(C) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel involved in the study.

(D) The test and control substances identified by name, chemical abstract (CAS) number or referenced code number, purity and composition, or other appropriate characteristics.

(E) Information regarding the stability of the test and control substances under all conditions of the study.

(F) A description of the methods and test standards used or a reference thereto.

(G) A description of the test system used or a reference thereto.

(H) A description of the quality assurance methods used to insure the quality of the data.

(I) A description of all circumstances that may have affected the quality or integrity of the data.

(J) A description of statistical methods employed for analyzing the data.

(K) A description, where applicable, of the transformation, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis. The analysis of the data must include a report of suitable statistical parameters, e.g., number of data points, standard deviation, coefficient of variation, regression coefficients, and confidence intervals, as appropriate.

(L) The locations where all specimens, raw data, and final report are stored.

(M) The statement prepared and signed by the quality assurance unit as described in paragraph (c)(4)(ii)(H) of this section.

(ii) The study director must sign the final report.

(iii) Corrections or additions to a final report must be written as an amendment by the study director. The amendment must clearly identify the part of the final report that is being amended or corrected and the reasons for the changes, and must be signed and dated by the person responsible. Alternatively, the final report may be reissued with references to the report it replaces so that no part of the record is lost.

(iv) In addition to the reporting requirements as described in paragraph (h)(1) (i) to (iii) of this section, additional reporting requirements, including the report format, may be specified in appropriate test standards and rules.

(2) *Storage and retrieval of records and data.* (i) All raw data, documentation, study plans, specimens and final reports generated as a result of a study must be retained as specified in paragraph (h)(3) of this section.

(ii) Archives must be used for orderly storage and expedient retrieval of all raw data, documentation, study plans, specimens, and interim and final reports. Conditions of storage must minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided the archives have specific reference to those other laboratories.

(iii) An individual must be identified as responsible for the archives.

(iv) Only authorized personnel may enter the archives.

(v) Material retained or referred to in the archives must be indexed by test substance or mixture, sponsor, date of study, test system, and nature of study.

(vi) In addition to the requirements for the storage and retrieval of records and data as described in paragraph (h)(2)(i) through (v) of this section, other requirements may be specified in appropriate standards and rules.

(3) *Retention of records.* (i) Record retention requirements set forth in these standards do not supersede the record retention requirements of any other pertinent regulation.

(ii) Except as provided in paragraph (h)(3)(iii) of this section, raw data, documentation, records and specimens pertaining to a study and required to be stored must be retained in the archives by the testing facility for at least 10 years from the date the final study report is submitted to the EPA.

(iii) Wet specimens, samples of test or control substances, samples of test or control substance carrier mixtures, and

specially prepared materials which are relatively fragile and change markedly during storage, must be retained only as long as the quality of the preparation affords evaluation. In no case will retention of such materials be required for more than 10 years after the conclusion of the study.

(iv) The master schedule sheet, copies of study plans, and records of quality assurance inspections, as required by paragraph (c)(4)(iii) of this section, must be maintained by the quality assurance unit as an easily accessible system of records for at least 10 years after the conclusion of the study.

(v) Summaries of personnel training and experience and job description required to be maintained by paragraph (c)(1)(iii) of this section must be retained along with all other testing facility employment records for at least 10 years after the conclusion of the study.

(vi) Records and reports of the maintenance, calibration, and inspection of equipment, as required by paragraph (e)(2)(ii) and (iii) of this section, must be retained for at least 10 years after the conclusion of the study.

(vii) If a facility conducting testing goes out of business, all raw data, documentation, and other materials specified in this section must be transferred to the archives of the sponsor of the study. The EPA must be notified in writing of such a transfer.

(i) *Inspection of a testing facility.* A testing facility must permit an authorized employee of the EPA to conduct inspections and audits.

§ 772.110–3 Physical, chemical, and persistence testing.

(a) *Scope and purpose.* The provisions contained in this section are in addition to the general provisions set forth in § 772.110–2. They address items that are specific to physical, chemical, and persistence testing.

(b) *Personnel*—(1) *General requirements.* (i) The physical, chemical, and persistence test procedures must be performed and supervised by chemists, microbiologists, and soil scientists with demonstrated competence in performing the types of test procedures specified.

(ii) The analyst must perform, with minimal supervision, in those specialties for which the analyst is qualified by education, training, and experience.

(iii) The supervisor must direct technical personnel in the proper performance of laboratory procedures and the reporting of results.

(2) *Specific requirements*—(i) *Analyst*—(A) *Academic training.* An analyst must have a minimum of a high school diploma or its equivalent.

(B) *Experience.* An analyst must have a minimum of one year of experience in laboratory testing plus a minimum of 3 months on-the-job experience in performing the measurements being considered.

(C) *Supervision.* An analyst must be supervised by an experienced professional scientist.

(ii) *Supervisor*—(A) *Academic training.* A supervisor must have a minimum of a Bachelors degree in chemistry, microbiology, biology, or closely related fields as appropriate to the assigned area of responsibility.

(B) *Experience.* A supervisor must have a minimum of 2 years on-the-job experience with the general types of measurements being considered.

(C) *Laboratory requirements.* (1) Laboratory space must be adequate to accomodate the periods of peak workload. Working space requirements must include sufficient bench-top area for processing samples; storage space for chemicals, glassware and portable equipment items; floor space for stationary equipment (refrigerators, centrifuges, shakers, etc.); and associated areas for cleaning glassware and sterilizing materials or media.

(2) The microbiological studies involved the use of sewage from domestic wastewater treatment plants. Consequently, individuals performing these tests may be exposed to microbial agents that are hazardous to human health. All individuals working with those tests or in the vicinity of those sewage samples must be made aware of the potential hazard and take appropriate steps to minimize the hazard. It is recommended that all individuals who conduct biodegradation tests be immunized against typhoid and tetanus within the five year period preceding the starting date of the test. The sparging of test flasks shall be conducted in a laboratory hood that is vented to the atmosphere.

(3) The study director must take appropriate measures for the protection of all individuals who will handle or may be exposed to the test material.

§ 772.110–4 Ecological effects testing.

(a) *Scope and purpose.* The provisions contained in this section are in addition to the general provisions set forth in § 772.110–2. They address items that are specific to ecological effects testing.

(b) *Personnel*—(1) *General requirement.* Any individual found at any time to have an illness that may adversely affect the quality and integrity of the study must be excluded from direct contact with test systems, test and control substances, and any other operation or function that may adversely affect the study, until the condition is corrected. All personnel must be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to adversely affect a study.

(2) *Specific requirements.* (i) A biologist (or other professional) with adequate training and experience in a pertinent discipline must perform or directly supervise all studies conducted with test animals or plants. Important qualifications for laboratory personnel performing such studies include, but are not limited to, education, experience in growing and testing the organisms being selected or their taxonomically close reltives, and adequate knowledge of culture methods, life cycles, and environmental requirements of the test organisms.

(ii) A microbiologist, or other professional, with adequate training and experience must perform or directly supervise all microbiological tests.

(iii) A Board-certified or Board-eligible veterinarian (or other professional) with adequate training and experience in the pertinent disciplines shall ascertain health status of all terrestrial vertebrate test animals prior to the study and be responsible for the general health and care of all such test animals during the experiment. This individual must supervise all laboratory animal care technicians. An experienced aquatic or fisheries biologist must ascertain the health status of all aquatic test animals and be responsible for the general health and care of all aquatic test animals.

(iv) A Board-certified or Board-eligible pathologist (or other professional) with appropriate experience in pathobiology must perform or directly supervise all necropsies, approve the methods and procedures used in the preparation of all histopathologic material, and assist in the final analysis of all pathology data. In addition, such an individual must conduct all microscopic analyses and render all histopathologic diagnoses.

(v) The chemist who provides analytical services must have the education, training, and experience for performing accurate chemical analyses of organic and inorganic compounds that may be found in water, soil, air, and biological samples taken during the tests and must be skilled in separation and instrumental techniques required in such analyses. Instruments that may be required for these analyses include, but are not limited to, gas and liquid chromatographs with various detectors and ultraviolet, infrared, nuclear magnetic resonance, mass, and atomic absorption spectrometry.

(vi) A technician with adequate training, experience, and capability must be responsible for the preparation of all histological material. The technician may, under direct supervision of the pathologist, perform the animal necropsies. Certification of the technician by the American Society of Clinical Pathology (ASCP) is acceptable as proof of adequate training in all cases.

(vii) A technician with adequate training, experience, and capability must be responsible for all general laboratory animal observation, handling, care, and feeding. In addition, the technician must be responsible for sanitation, observation of climate control, and the recording of routine data. The technician may also perform other tasks under the supervision of the veterinarian. The technican may, under the direct supervision of the pathologist, perform the animal necropsies. Certification of the technician by the American Association of Laboratory Animal Science (AALAS) is acceptable as proof of adequate training in all cases.

(viii) For aquatic animal studies, a technician with the training, experience, and capability to successfully maintain aquatic vertebrates and invertebrates must be responsible for the general laboratory animal observation, handling, care, and feeding. The technician must also handle the sanitation duties, observe environmental controls (e.g., water flow rate, temperature, salinity, dissolved oxygen, etc.), and record routine data. The technician may perform, under the supervision of a professional such as a biologist or veterinarian trained in fishery management, fish disease, pathology, and physiology, and other pertinent fields, other tasks for which the technician is qualified, e.g., preparation of test mixtures, administration of test chemicals, obtaining samples for chemical analyses, making growth measurements, etc. The technician may, under the direct supervision of the pathobiologist, or other professional serving in lieu of a pathologist, perform the animal necropsies.

(ix) In addition to the specific personnel requirements as described above, further personnel requirements may be specified in appropriate test standards and test rules.

(c) *Facilities*—(1) *Test organism care facilities.* (i) General provisions to be followed are outlined in the Animal Welfare Act of 1970 (Pub. L. 91–579) as set forth in 9 CFR Part 3, and in "Guide for The Care And Use of Laboratory Animals" which is incorporated by reference. It is DHEW Publication No. (NIH) 78–23 and is for sale from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. When ordering use GPO Stock No. 017–040–00427–3. It is also available for inspection at the Office of the Federal Register Information Center, Room 8391, 1100 L Street, NW., Washington, DC 20408. Additional provisions may be found in the report "Long-Term Holding of Laboratory Rodents" which is incorporated by reference. It is a report of the Committee on Long-Term Holding Of Laboratory Rodents of the Institute of Laboratory Animal Resources, Assembly of Life Sciences, National Research Council and was published in ILAR News, volume XIX, Number 4, 1976. Copies may be obtained from the Document Control Officer, Management Support Division (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room 447, 401 M Street SW., Washington, DC 20460. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street, NW., Washington, DC 20408. For avian species, the requirements as described in the proposed regulations of 40 CFR 163.71–2 and 163.71–4 apply. Further guidance is given in "Quality Assurance Guidelines for Biological Testing" which is incorporated by reference. It is EPA Publication No. EPA–600/4–78–043 and is for sale by the National Technical Information Service (NTIS), Springfield, VA 22161. When ordering use NTIS Stock No. PB–285 369. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street, NW., Washington, DC 20408. Additional guidance is in "Bioassay Procedures for the Ocean Disposal Permit Program" which is incorporated by reference. It is EPA Publication No. EPA–600/9–78–010 and is available from EPA, Office of Research and Development, Technical Information Staff, Cincinnati, OH 45268. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street NW., Washington, DC 20408. Further guidance may be found in "Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians" which is incorporated by reference. It is EPA Publication No. EPA–660/3–75–009 and is for sale from the National Technical Information Service (NTIS), Springfield, VA 22161. When ordering use NTIS Stock No. PB–242 105. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street NW., Washington, DC 20408.

(ii) A testing facility must have a sufficient number of rooms or areas for test organisms, to assure compliance with the study plan specifications in:

(A) Separation of species or test systems.

(B) Isolation of individual projects.

(C) Quarantine of animals and plants.

(D) Routine and specialized housing of test organisms. Plants, microorganisms, or aquatic animals of different species need not be housed in separate rooms, provided they are adequately segregated to avoid mix-up and cross contamination. Stocks of animals from which test animals are drawn must be housed separately from those undergoing testing.

(iii) A testing facility must have a number of rooms or areas for test organisms separate from those described in paragraph (c)(1)(i) of this section to ensure isolation of studies being done with test systems or test and control substances known to be biohazardous. Such rooms or areas must be maintained in compliance with OSHA regulations to ensure the health and safety of personnel.

(iv) Separate areas must be provided for the diagnosis, treatment, and control of laboratory plant and animal diseases. These areas must provide effective isolation for the housing of test organisms either known or suspected of being diseased or of being disease carriers.

(v) Facilities must exist for the collection and disposal of all waste from test organisms and for safe sanitary storage of waste before removal from the testing facility. Disposal facilities must be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.

(2) *Supply and support facilities*—(i) *Animal supply facilities.* There must be storage areas for feed, bedding, supplies, and equipment. Feed and bedding storage areas must be protected against infestation or contamination. Refrigeration must be provided for perishable supplies and perishable feed.

(ii) *Plant supply and support facilities.* (A) There must be storage areas for equipment and supplies, and there must be receiving and holding areas for samples and plant material.

(B) There must be support facilities suitable for culturing and maintaining algae or aquatic plants, as specified in the study plan.

(C) There must be support facilities, as specified in the study plan, for plant growth (greenhouse, growth chamber, light banks) to maintain sanitary growth

conditions (insect-and weed-free) with provisions for sterilized media.

(D) Refrigeration must be provided for supplies and for holding plant material.

(3) *Laboratory operation areas.* (i) Separate laboratory space must be provided for the performance of the routine procedures required by studies, including specialized areas for activities such as aseptic procedures, intensive care, necropsy, histology, radiography, and handling of biohazardous materials, as specified in the study plans.

(ii) Separate space must be provided for cleaning, sterilizing, and maintaining equipment and supplies used during the study.

(iii) For the health and safety of personnel, separate space must be provided for locker, shower, toilet, and washing facilities, as required in regulations set forth by OSHA under Title 29 of the Code of Federal Regulations.

(d) *Testing facilities operation*—(1) *Standard operating procedures.* (i) Standard operating procedures must be established in conformance with the requirements of appropriate test standards. These should include, but not be limited to, the following:

(A) Test facility, animal room, greenhouse, incubators, preparation for study plan execution.

(B) Organism care.

(C) Laboratory tests, e.g., extraction of residues from tissue samples, extract cleanups, quantitation of residues, and identification of metabolites.

(D) Handling of organisms found moribund or dead.

(E) Postmortem examination of test organisms, necropsy of animals, plant pathology work-up.

(F) Collection and identification of specimens.

(G) Histopathology.

(H) Transfer, proper placement, and identification of test organisms.

(2) *Test organism care.* (i) There must be standard operating procedures for the housing, feeding, handling, and care of test organisms.

(ii) General provisions to be followed are outlined in the Animal Welfare Act of 1970 under 9 CFR Part 3, and in "Guide for The Care And Use of Laboratory Animals" which is incorporated by reference. It is DHEW Publication No. (NIH) 78–23 and is for sale from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. When ordering use GPO Stock No. 017–040–00427–3. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street, NW., Washington, DC 20408. Additional provisions may be found in the report "Long-Term Holding of Laboratory Rodents" which is incorporated by reference. It is a report of the Committee on Long-Term Holding of Laboratory Rodents of the Institute of Laboratory Animal Resources, Assembly of Life Sciences, National Research Council and was published in ILAR News, Volume XIX, Number 4, 1976. Copies may be obtained from the Document Control Officer, Management Support Division (TS–793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Room 447, 401 M Street SW., Washington, DC 20460. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street, NW., Washington, DC 20408. All animals for which there are no specific regulations should be housed, fed, and handled in compliance with Subpart E of 9 CFR Part 3. Avian care rcommendations for bobwhite quail and mallard ducks (40 CFR 163.71–2 and 163.71–4) should be followed as appropriate for other species. Aquatic macroinvertebrates, fish, and other aquatic animals should be handled and maintained according to the guidance given in "Quality Assurance Guidelines for Biological Testing" which is incorporated by reference. It is EPA Publication No. EPA–600/4–78–043 and is for sale by the National Technical Information Service (NTIS), Springfield, VA 22161. When ordering use NTIS Stock No. PB–285 369. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street NW., Washington, DC 20408. Additional provisions may be found in "Bioassay Procedures for the Ocean Disposal Permit Program" which is incorporated by reference. It is EPA Publication No. EPA–600/9–78–010 and is available from EPA, Office of Research and Development, Technical Information Staff, Cincinnati, OH 45268. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street NW, Washington, DC 20408. Further guidance may be found in "Methods for Acute Toxicity Tests with Fish, Macroinvertebrates, and Amphibians," which is incorporated by reference. It is EPA Publication No. EPA–660/3–75–009 and is for sale from the National Technical Information Services (NTIS), Springfield, VA 22161. When ordering use NTIS Stock No. PB–242 105. It is also available for inspection at the Office of the Federal Register Information Center, Room 8301, 1100 L Street NW., Washington, DC 20408. Aquatic and terrestial plants are to be cultured according to the test standards cited in the applicable test rule. If the study so requires, deviation from the standard, e.g., use of restraining devices, is acceptable, provided there is adequate documented justification of the need for such deviation. Such documentation shall be retained as part of the records of the study.

(iii) All newly received test organisms from outside sources must be placed in quarantine until their health status (including disease or parasitism) has been evaluated. The evaluation of animals (including mammals and birds) must be done in accordance with acceptable scientific practice. The test organism source, date of arrival, and the health status of the test organisms must be recorded as a part of the raw data.

(iv) At the initiation of a study, test organisms must be free of any disease or condition (such as residual therapeutic agents) that might interfere with the purpose or conduct of the study. If, during the course of the study, the test organisms contract such a disease or condition, the diseased test organisms must be isolated. If necessary, such test organisms may be treated for disease or signs of disease provided such treatment does not interfere with the study and all test organisms in the study receive the same treatment. However, unless a strong rationale, approved by the sponsor and the Environmental Protection Agency, can be set forth, the study should be terminated and begun again with new test organisms. The diagnosis, authorizations of treatment, description of treatment, and dates of treatment must be documented and the documents retained.

(v) Organisms must be treated in accordance with specific study plans, which will include provisions for identification of individuals or groups at all stages of handling. Warm-blooded animals, terrestrial reptiles, and amphibians used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and return to their home cages for any reason (e.g., cage cleaning, treatment, etc.) must be unequivocally identified via tattoo, toe clip, color code, ear tag, ear punch, etc. All information needed to identify each animal within an animal-housing unit must be placed on the outside of that unit.

(vi) Different species, or organisms of the same species but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to control or test substances or test organism mix-up could affect the outcome of either study. If such mixed

housing is necessary, adequate differentiation by space and identification must be made.

(vii) Cages, racks and accessory equipment, pens and enclosures, aquaria, holding tanks and ponds, and other equipment and support areas must be cleaned and sanitized at appropriate intervals. Other test organism holding, rearing, breeding, and housing areas and equipment must be cleaned and, as appropriate, sanitized to an equivalent extent.

(viii) Feed and water used for the test organisms must be analyzed periodically to ensure that contaminants capable of interfering with the study and reasonably expected to be present in such feed or water do not exceed levels specified in the study plans. Documentation of such analyses must be kept as raw data.

(ix) Bedding used in animal cages or pens must not interfere with the purpose or conduct of the study and must be changed as often as necessary to keep the animals dry and clean.

(x) For marine aquatic tests, an adequate supply of clean sea water or artificial sea water (prepared from deionized or distilled water and sea-salt mixture) is required. The ranges of composition will be as specified in the test standards. For fresh-water tests, an adequate supply of clean water of the proper hardness, pH, and temperture, and devoid of contaminants, is mandatory.

(xi) The use of any pest control materials must be documented. Use of cleaning materials and pest control materials that interfere with the study must be avoided.

(e) *Study plan and conduct of a study*—(1) *Study plan.* (i) The approved written study must include, but not be limited to, the following:

(A) Where applicable, the justification for selection of the test organisms, the number of test organisms used, their sex, age, body weight range, source of supply, species, strain, and substrain.

(B) Where applicable, the procedure for identification of individuals or groups of the test organisms.

(C) Where applicable, a description and/or identification of the diet used in the study as well as kinds and concentrations of solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control substances before mixing with the carrier. The description must include specification for acceptable levels of contaminants reasonably expected to be present in the dietary materials and known to be capable of interfering with the purpose or conduct of the study if levels exceed those established by the specifications.

(D) Where applicable, the route of administration and the reason for its choice.

(E) Where applicable, each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control substance to be administered, and the method and frequency of administration.

(F) Where applicable, the method by which the degree of absorption of the test and control substances by the test system will be determined to achieve the objectives of the study.

(2) *Conduct of a study.* (i) Where applicable, specimens must be identified by test system, study, nature, and date of collection. This information must be located on the specimen container or accompany the specimen in a manner that avoids error in the recording and storage of data.

(ii) Where applicable, records of gross findings for a specimen from postmortem observations must be available to the pathologist examining that specimen histopathologically.

(f) *Reporting of study results.* (1) The final report must include, but not be limited to the following:

(i) Where applicable, the number of test organisms used, sex, age, body weight range, source of supply, species, strain, substrain, and procedure used for identification of groups or individuals.

(ii) Where applicable a description of the dosage, dosage regimen, route of administration and duration.

[FR Doc. 80-36046 Filed 11-20-80; 8:45 am]
BILLING CODE 6560-31-M